ENGLISH

CRANEX® 3D

Digital Panoramic X-Ray System

User Manual

206718 rev. 5

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CE
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1 Introduction

1.1 CRANEX® 3D

CRANEX® 3D is a dental x-ray system for producing high quality digital images of dentition, TM-joints and skull. In order to take images with CRANEX® 3D you need a suitable PC hardware connected to the CRANEX® 3D unit and SCANORA® software to capture and manage images.

CRANEX® 3D performs the following procedures:

Panoramic

- Adult panoramic
- Child panoramic (Reduced width and height)
- Bitewing
- TMJ, PA projection
- TMJ, lateral projection (axially corrected)
- Maxillary sinus

Cephalometric (optional)

- Cephalometric Full size Lateral
- Cephalometric Reduced size lateral
- Cephalometric posterior-anterior projection PA/AP
- Reverse Towne projection
- Waters view
- Carpus program (optional)
  (Not available in USA and Canada)

3D (optional)

- XS 61x41 mm Field of View
- Midi 61x78 mm Field of View
- Endo 61 x 41 mm Field of View

1.2 References

The following instructions are delivered with in the CRANEX® 3D installation manual:

- Firmware update instructions
- Calibration instructions
- Cephalostat upgrade instructions
- Cephalostat side changing instructions

The following instructions are separate and can be ordered from customer service:

- 3D upgrade instructions are delivered with the 3D upgrade kit

1.3 Intended use

CRANEX® 3D must only be used and operated by dentist and other qualified professionals. CRANEX® 3D must only be used to take panoramic, cephalometric and 3D images of the dento-maxillofacial complex of the human skull. It must not be used to take images of any other part of the human body.

Panoramic and 3D exposures should not be used if conventional intraoral radiographic images (bitewing exposures) would be sufficient.

Cone beam computed tomography images are not adequate for the analysis of soft tissue.

CAUTION! *USA only: Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.*

1.4 Associated documentation

- CRANEX® 3D user manual
- CRANEX® 3D installation manual
- The SCANORA® software user manual
- The SCANORA® software installation manual
- The user manual supplied with the dental imaging software
- The installation manual supplied with the dental imaging software
- The user manual supplied with the 3D imaging software
- The installation manual supplied with the 3D imaging software

1.5 Abbreviations used in this manual

FOV = Field Of View. The cylindrical 3D volume that is reconstructed by the system.

ROI = Region Of Interest. The anatomical area or region of the patient that you are interested to examine.

AES = Automatic Exposure Setting

1.6 Warnings and precautions

1.6.1 Warnings to be observed during use

The unit may be dangerous to the user and the patient, if the safety regulations in this manual are ignored, if the unit is not used in the way described in this manual and/or if the user does not know how to use the unit.

The unit must only be used to take the dental x-ray exposures described in this manual. The unit must NOT be used to take any other x-ray exposures. It is not safe to use the unit to take x-ray exposures, that it is not designed for.

Only professionally qualified dental and/or medical personnel are allowed to operate the unit and carry out any diagnoses based on output from the unit.

Because the x-ray limitations and safety regulations change from time to time, it is the responsibility of the user to make sure that all the valid safety regulations are fulfilled.

When taking an x-ray exposure of a patient with exceptional anatomy (typically very tall or large) use the Test-mode (no x-rays) first to make sure that patient can be positioned correctly to the unit and for checking that the unit doesn't hit the patient.

Operator should maintain visible contact with the patient and technique factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.

It is the responsibility of the doctor to decide whether x-ray exposure or any additional exposures are justified and necessary.

The minimum height of patient that can be x-rayed is 120 cm (3.9ft / 47.2in) and the maximum is 200 cm (6ft /78in). These heights only apply to patients with normal anatomy.

Always use the lowest suitable x-ray dose to obtain the desired level of image quality.

Avoid taking x-ray exposures of pregnant women.

When taking an x-ray exposure of a child always use the lowest possible x-ray dose, the smallest possible image area and the lowest possible resolution that allows you to perform the required diagnostic task.

If the patient is using a pacemaker, consult the manufacturer of the pacemaker before taking an exposure to confirm that the x-ray unit will not interfere with the operation of the pacemaker.

Decontaminate all the surfaces that the patient is in contact with after every patient to prevent cross infection.

Decontaminate all device accessories that contact the patient during a radiographic examination.

Do not open or remove any of the unit's enclosures. No user serviceable parts inside.

The customer must ensure that the siting environment fulfills the requirements listed in the Installation manual. Special attention must be paid to the strength of the floor and wall materials, electrical mains and radiation protection. It is the responsibility of the customer to ensure that the site is large enough for the patients.

The unit contains toxic materials that need to be handled properly when disposing the unit. Return the unit to the dealer in the end of its life cycle.

Excessive dust should be cleaned from the unit for free airflow and cooling. Switch of the unit before cleaning.

Always follow the instructions for patient positioning and imaging procedures instructed in the User Manual.

1.6.2 Warnings for cross infection

Always use available disposable protective covers with the patient positioning accessories:
Bite block cover
Chin plane cover
TMJ support cover
Lip holder cover
Chin cup cover

1.6.3 General warnings

Personnel operating the device must be adequately trained with respect to the technological principles of operation and radiation protection when using cone beam computed tomography (CBCT) imaging.

This unit complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. shall not be used in close proximity of the unit as they could influence the performance of the unit.

The correct software and settings in the workstation are essential to the performance of the unit. Consult technical support to ensure correct setup.

Danger: Explosion hazard - do not use in the presence of flammable anesthetics, gases or vapors.

The unit is factory set to operate using a 230-240 ±10 VAC power supply. Never connect the unit to a power supply different to the voltage marked on the unit.

The site must fulfill the environmental requirements in the installation manual chapter technical specifications.

There should be free space around the unit for safe operation.

To maintain patient safety it is mandatory to use an unshielded CAT6 Ethernet cable between the unit and the network or workstation, so that multiple chassis are not connected. Non-medical grade PC should not be used in patient environment.

This product itself complies with IEC 60601-1 medical safety standard but in order to the system incorporating also a PC to comply the standard, EITHER the PC has to be a medical PC OR the PC has to be located over 1,5 meters apart from the unit. The installer and the user of the system shall confirm that at least one of the above requirements is fulfilled. A PC is a medical one if it complies IEC 60601-1 standard and that is indicated in the accompanying documents of the PC. See chapter Technical specifications, Minimum PC Requirements, in user manual.

All service operations must be made by authorized service personnel only.

The annual service as described in manual is mandatory for the correct and safe operation of the unit.

When taking exposures, operators and service personnel must protect themselves from radiation and remain at least two meters (six feet) away from the unit during exposure. Protect the patient from scattered radiation by placing a protective lead apron over the patient.

The unit must be installed and serviced according to the unit Installation & adjustments manual by a qualified technician.

Only personnel trained and approved by the manufacturer of the unit are allowed to service the unit.

3D should not be used for routine or screening examinations in which a radiograph is taken regardless of the presence or absence of clinical signs and symptoms. 3D imaging examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.

Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the imaging should be done using conventional medical CT or MR, rather than 3D imaging using Cone Beam technology.

Make sure that patient's thyroid glands are protected by a lead apron during the exposure.

The place where the unit is to be installed and the position from where the user will take exposures must be correctly shielded from the radiation that is generated when the unit is operated. Ensure to fulfill or exceed the requirements of your local regulations.

The unit or its parts must not be changed or modified in any way without approval and instructions from the manufacturer.

When servicing use only approved replacement parts supplied by the manufacturer.

The use of accessories not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

If this device is used with 3rd party imaging application software not supplied by the manufacturer, the 3rd party imaging application software must comply with all local

laws on patient information software. This includes the Medical Device Directive 93/42/EEC and/or relevant legal requirements in the USA.

Do not connect any equipment to the unit that has not been supplied with the unit or that is not recommended by the manufacturer. The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

Mirror shall be closed before taking exposures.

1.7 Disclaimer

The manufacturer shall have no liability for consequential damages, personal injury, loss, damage or expense directly or indirectly arising from the use of its products. No agent, distributor or other party is authorized to make any warranty or other liability on behalf of the manufacturer with respect to its products.

1.8 Disposal

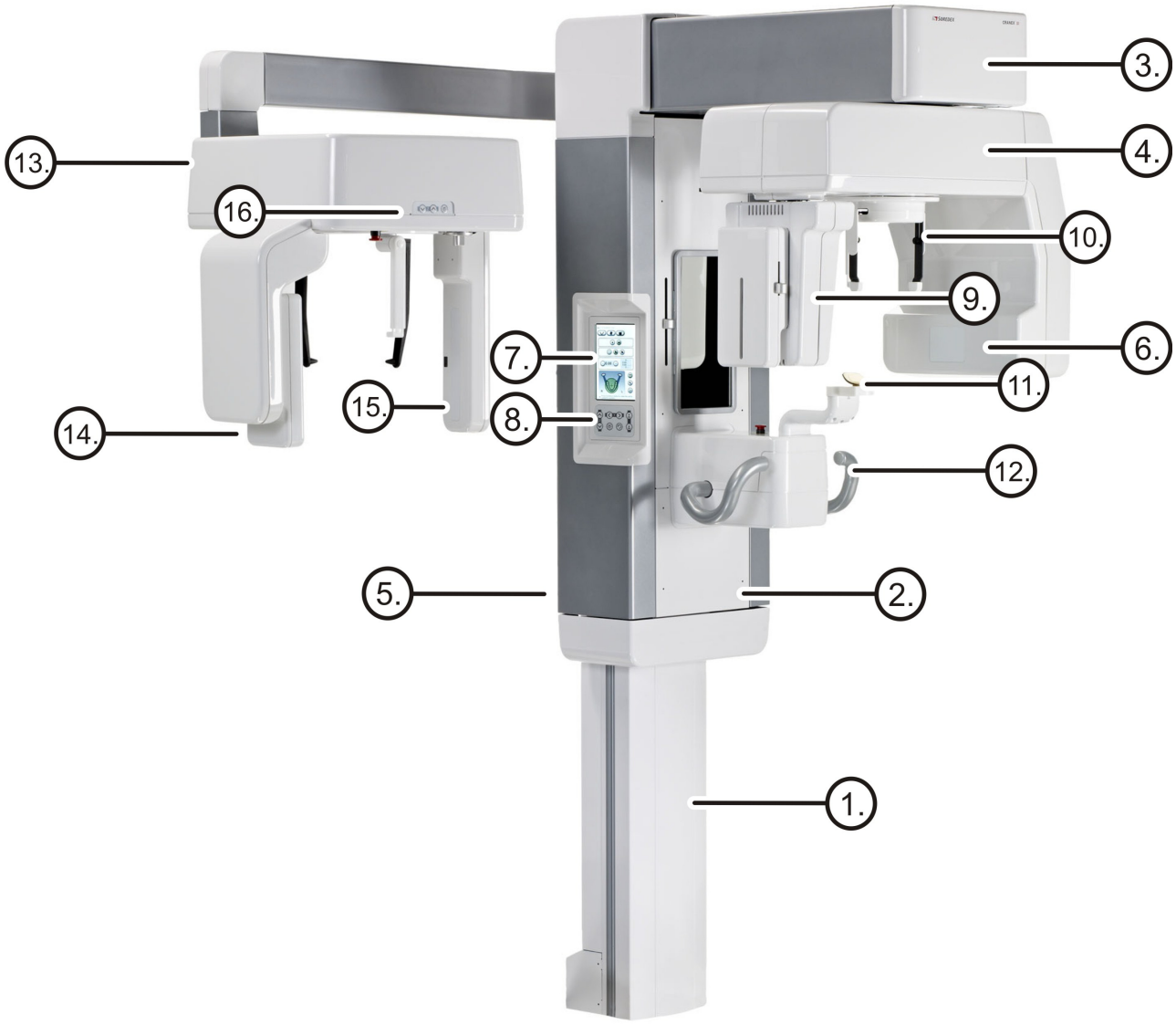
The device, its spare parts, its replacement parts and its accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

Unit has at least the following parts that should be regarded as nonenvironmental friendly waste products:

- Tubehead (Pb, oil)
- Collimator (Pb)
- All electronic circuits, electronic boards inside
- Sensor covers (EMC painted)

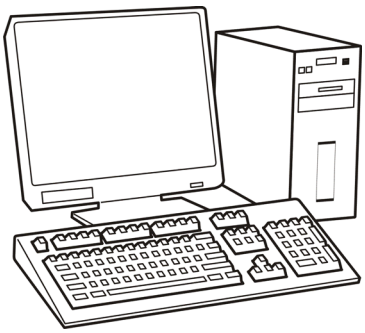
2 Unit description

2.1 Main parts and controls



1. Column
2. Carriage
3. Main support
4. Rotating unit
5. On / off switch (rear of carriage) and main fuses
6. Tubehead assembly
7. ClearTouch™ control panel
8. Positioning panel
9. Sensor head
10. Head support
11. Chin rest
12. Handles
13. Cephalometric unit
14. Cephalometric sensor
15. Secondary collimator
16. Positioning panel

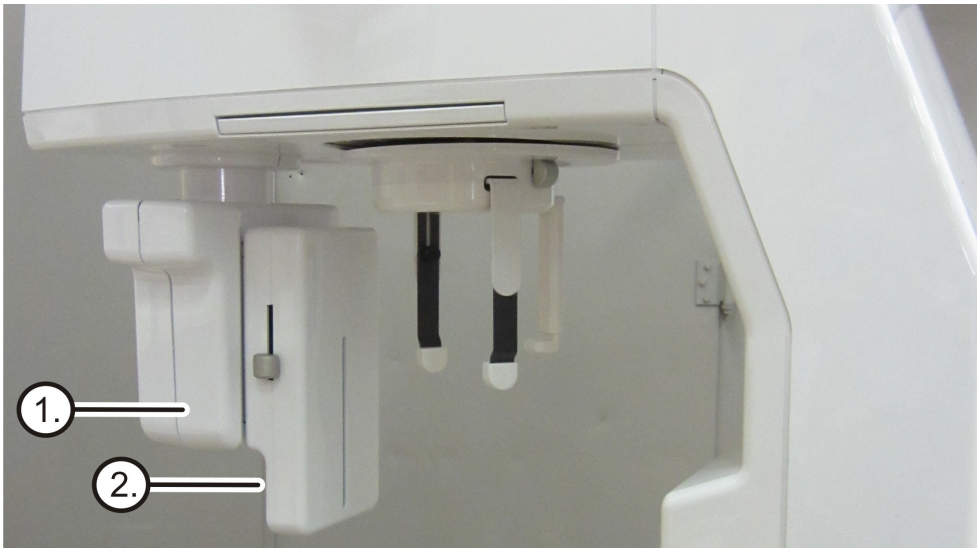
Fig 1.1.
On/off switch and main fuses



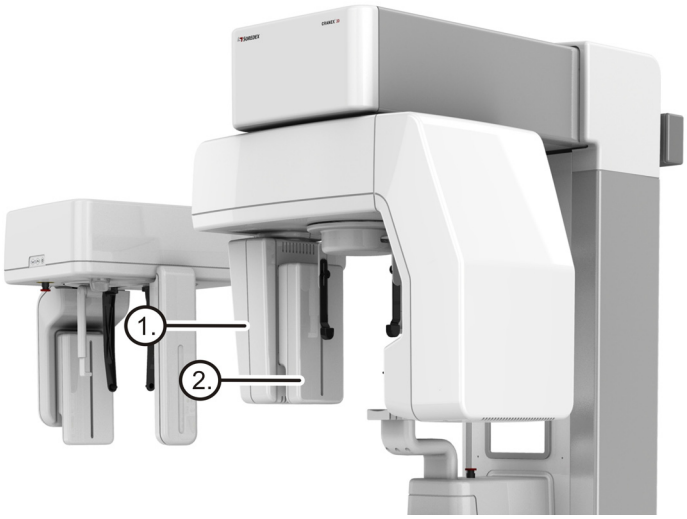
PC with MDD approved dental imaging software and 3D viewing software (not included).

All software must conform to the MDD and the relevant legal requirements in the USA.

The PC must conform to all the unit and dental imaging software requirements.

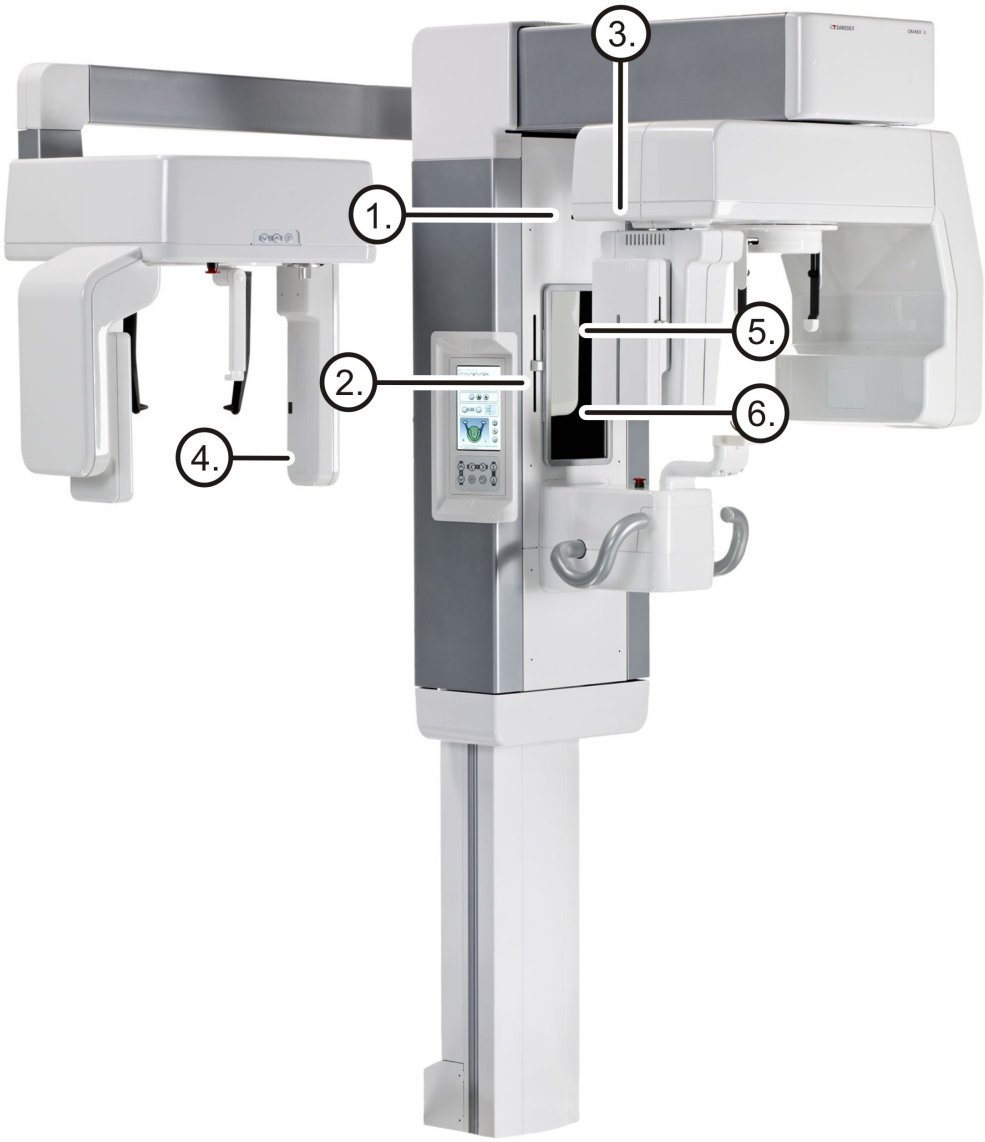


1. Sensor holder (PAN units only)
2. Panoramic sensor



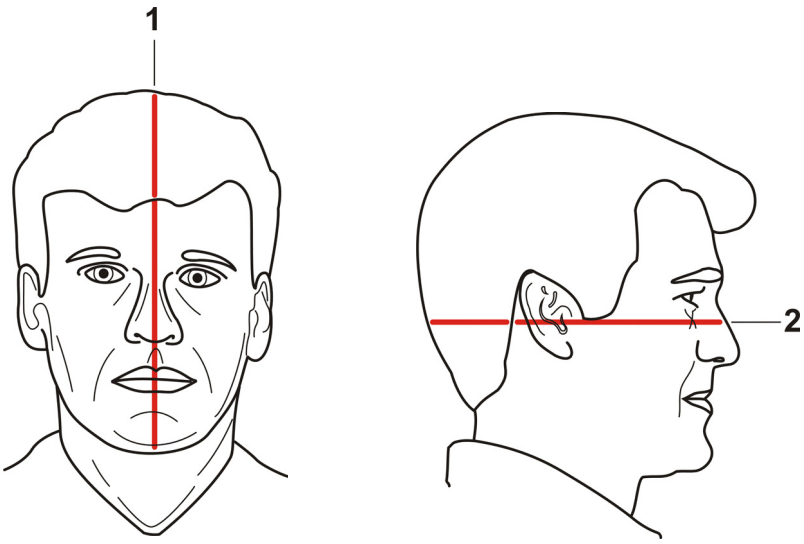
1. 3D sensor (units with 3D option)
2. Panoramic sensor

2.2 Patient positioning lights

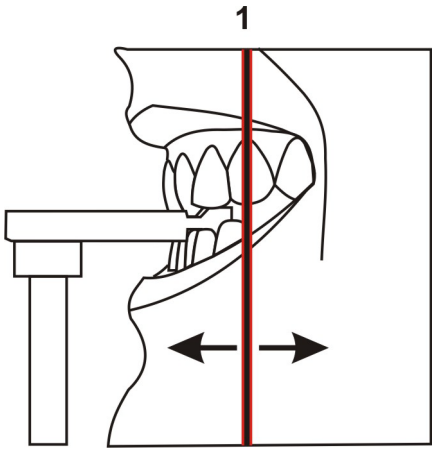


1. Midsagittal
2. Frankfort-horizontal
3. Focal trough
4. Cephalometric Frankfort horizontal
5. Horizontal, top of FOV (3D option only)
6. Horizontal, bottom of FOV (3D option only)

Panoramic lights

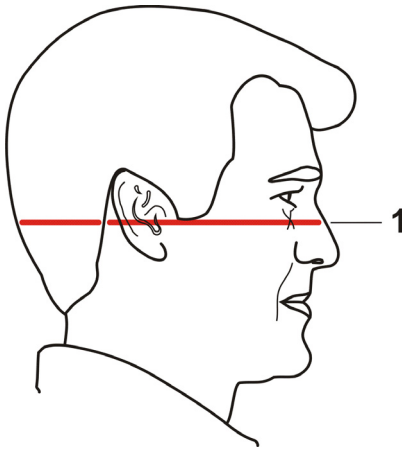


1. Midsagittal light
2. Frankfort-horizontal plane



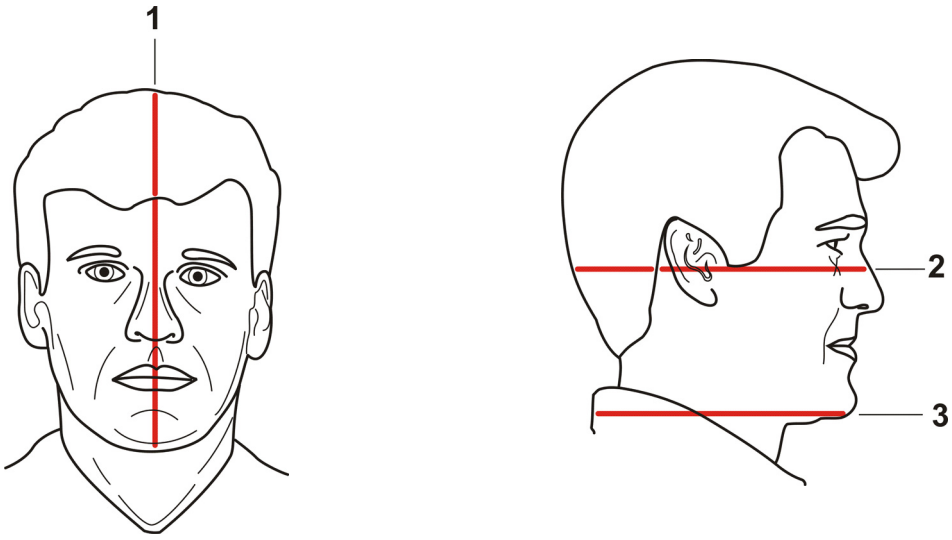
1. Focal through light

Cephalometric lights



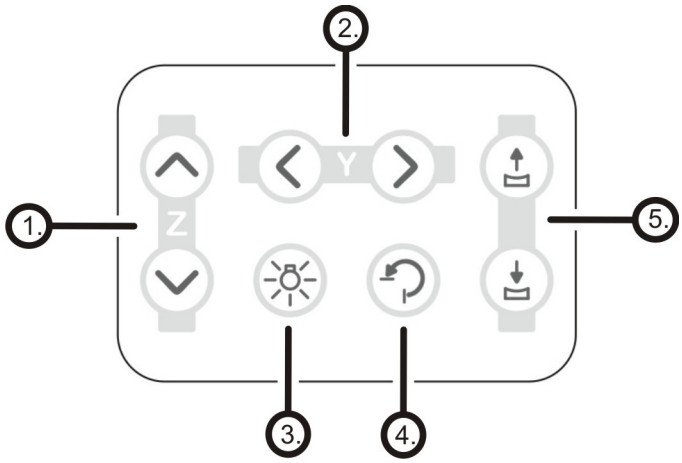
1. Frankfort-horizontal plane

3D lights



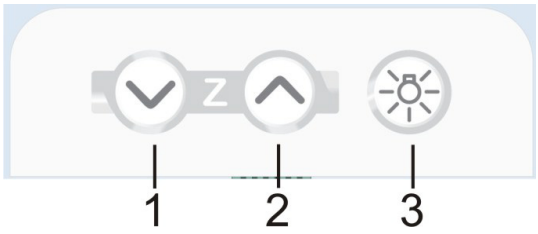
1. Midsagittal light
2. Horizontal light, top of FOV
3. Horizontal (H) light, bottom of FOV

2.3 Patient positioning panel



1. Carriage UP/DOWN (Z-movement)
2. Focal through adjustment (Y-movement)
3. Positioning lasers ON/OFF
4. Return
5. Chin support UP/DOWN

2.3.1 Cephalometric unit

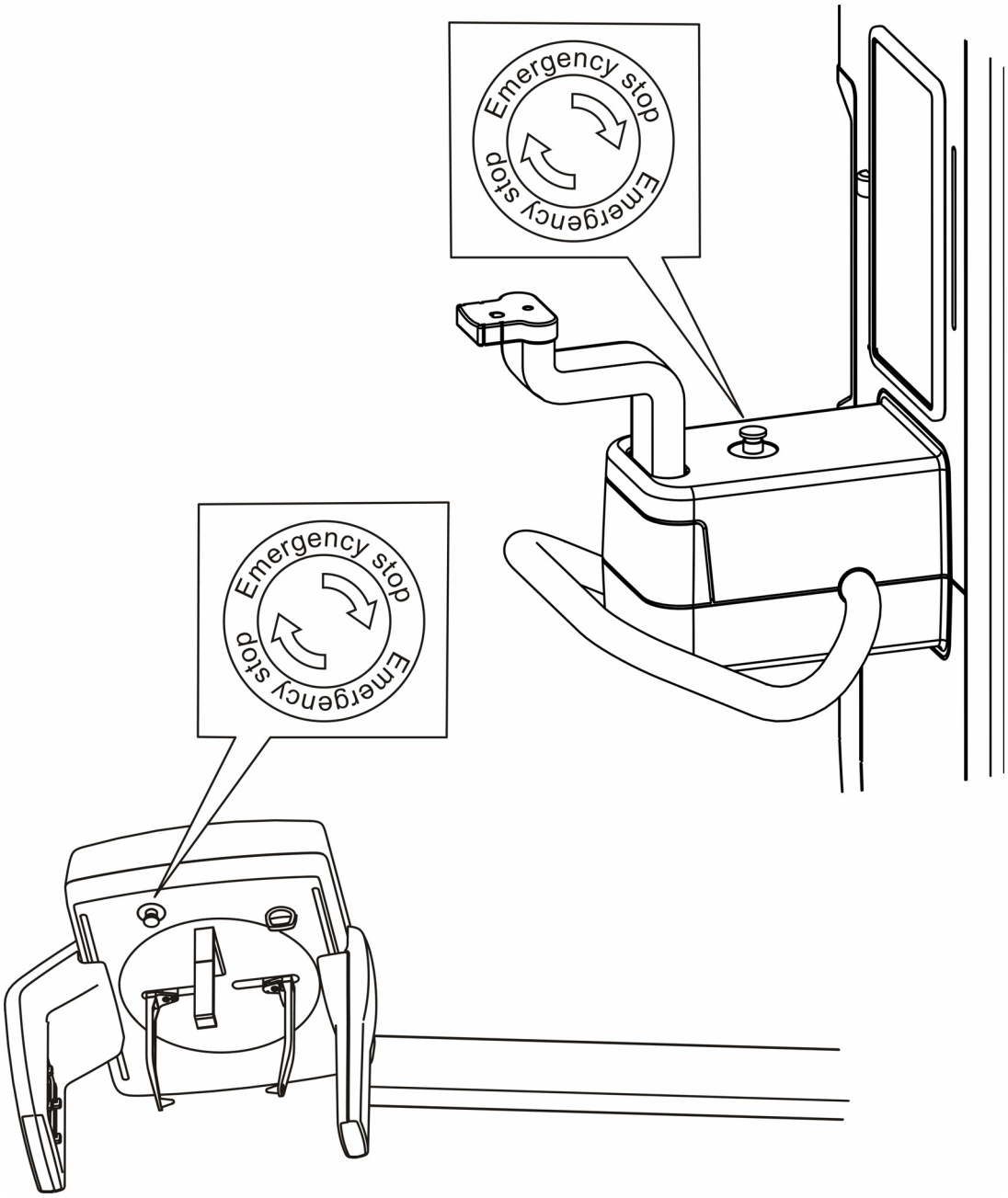


1. Carriage down
2. Carriage up
3. Positioning lights ON/OFF

2.4 Emergency stop switch

In case of malfunction of the exposure button or other protective devices of the unit, an emergency stop switch is provided near the handles and on the roof of the cephalostat head so that the patient can reach it.

If the emergency stop switch is pressed during an exposure, the exposure is terminated immediately and the x-ray unit is completely stopped. An interrupted exposure cannot be continued later, but has to be retaken from the beginning.

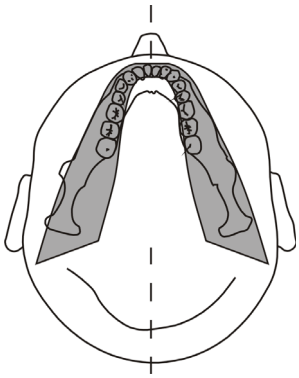


Press to stop the unit, rotate to release.

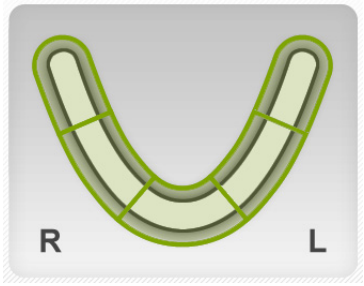
3 Imaging programs

3.1 Panoramic programs

Adult: Magnification 1.3

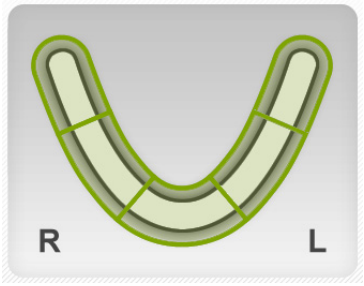


Panoramic imaging provides general view of dental and facial anatomy based on panoramic imaging technic.

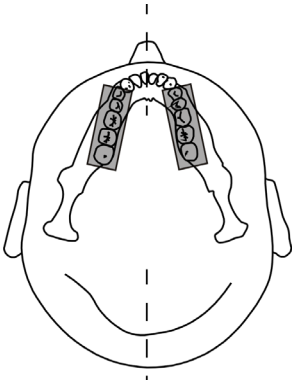


Adult panoramic 20,5 cm width x 11 cm height.

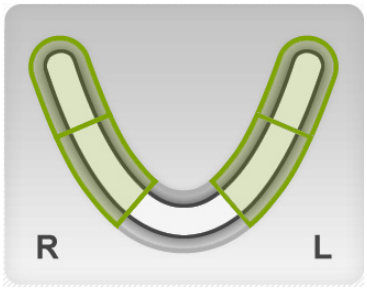
Child: Magnification 1.3



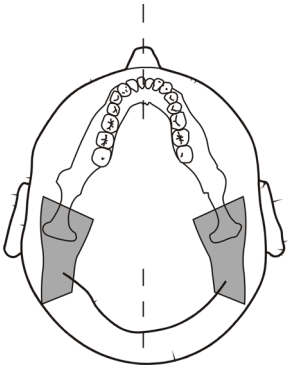
Child panoramic 11,5 cm width x 8,5 height**.**
Child panoramic has reduced width and height. Children can be imaged with less radiation dosage and shorter exposure time. Patients with jaw more narrow than average jaw can be exposed with this too.



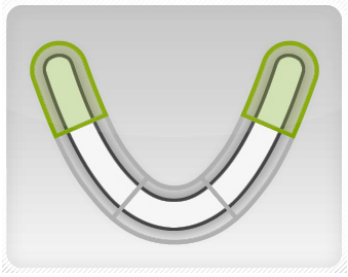
Bitewing: Magnification 1.3

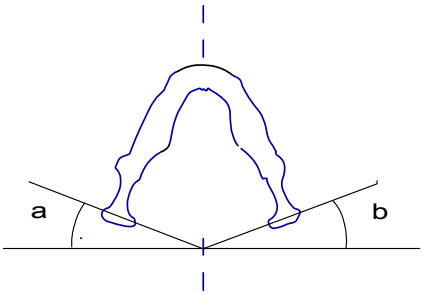


An orthogonal view of the dentition from the canine and posterior.

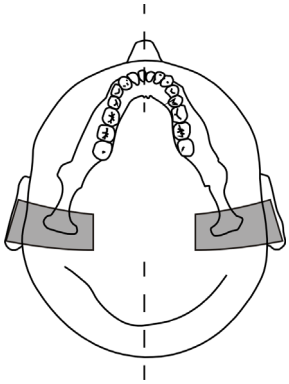


Lateral TMJ: Magnification 1.23



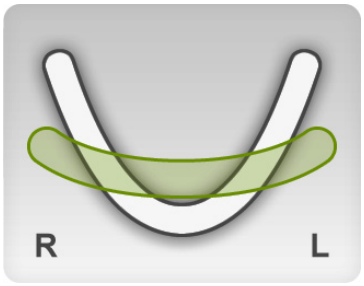


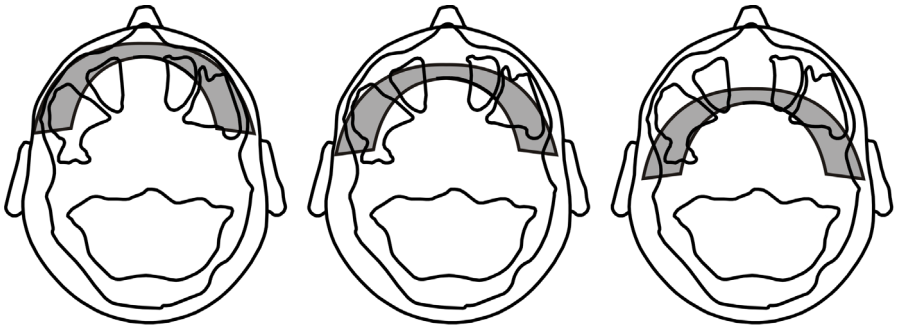
Lateral TMJ program provides a wide layer axially corrected views for the patient's left and right temporomandibular joints.



PA TMJ: Magnification 1.55

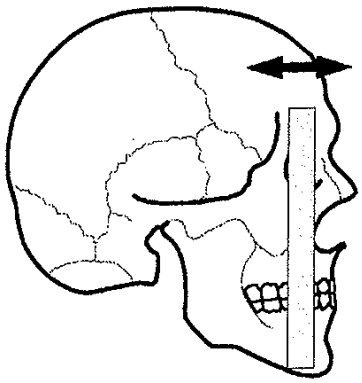
Maxillary Sinus: Magnification 1.3





Mesial 10 mm Start Distal 10 mm

Maxillary Sinus program produces a pan - tomographic layer through the posterior maxillary sinus. The layer is flatter than the standard panoramic programs and is moved 18 mm backward. These images are helpful in visualizing the mid and posterior maxillary sinus.

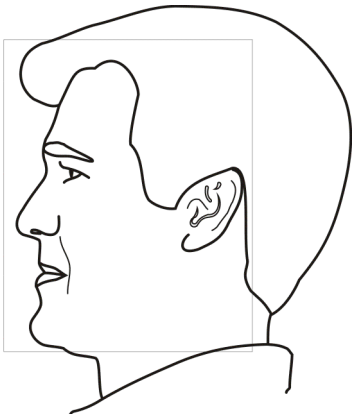


3.2 Cephalometric programs

Cephalometric programs provide central projection images of patient skull and dental anatomy. Images are utilized in ortodontics and general diagnostics.

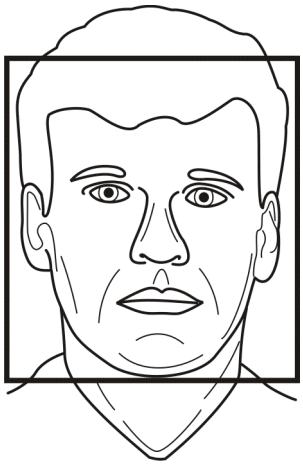
Full size lateral: Magnification 1.15

Field size: 22 x 26 cm (height x wide).
Lateral Cephalostat uses a full height image field.



Reduced size lateral

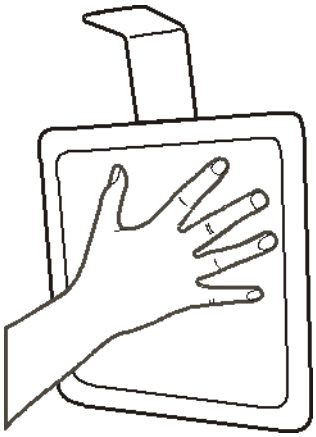
Field size: 22 x 18 cm (height x wide).
Reduced Width Lateral program has an optimized image width that is used e.g. for pediatric patients but also adult patients to reduce the radiation dose.



Cephalometric posterior-anterior (PA): Magnification 1.15

PA 22 x 20 cm (height x wide)

Carpus program (optional)
(Not available in USA and Canada)



Requires separate holder, not part of standard delivery.

3.3 3D programs

Cone beam 3D imaging enables seeing dentomaxillofacial anatomy of selected Field of View, FOV, helping with diagnostics and treatment planning. With 3D viewing software, user is able to analyze FOV area from multiple directions and see cross-sectional images from the area of interest.

XS FOV 61 x 41 mm (height x diameter)

High resolution (133µm voxel size)

Standard resolution (200µm voxel size)

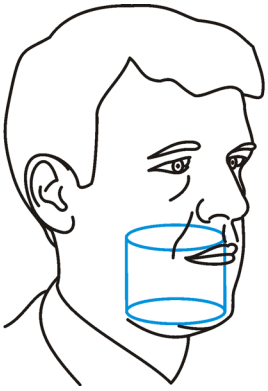
Endo FOV 61 x 41 mm (height x diameter)

Program for optimized endodontic imaging.

Endo program (85µm voxel size)

Midi size FOV 61 x 78 mm (OPTIONAL)

Standard resolution or High resolution.



High resolution (200µm voxel size)

Standard resolution (300µm voxel size)

3.4 Exposure settings for 3D imaging

Exposure settings for 3D imaging							
Note! *Voltage settings is always 90kV with unit 3D modality.*							
Resolu-tion	**FOV (h x w)**	**Expo-sure time**	**Scanning time**	**Amount of projec-tions**	**mA Low dose (DAP mGycm2)**	**mA High-quality (DAP mGycm2)**	**mA High-quality (DAP mGycm2)**
High Res	61 x 41 mm	6,1 s	10 s	608	6.3 mA (298)	8 mA (379)	13 mA (593)
Std Res	61 x 41 mm	2,3 s	10 s	230	8 mA (145)	10 mA (181)	13 mA (227)
High Res	61 x 78 mm	12,6 s	20 s	1260	5 mA (491)	6.3 mA (619)	10 mA (983)
Std Res	61 x 78 mm	4,9 s	20 s	460	8 mA (302)	10 mA (372)	13 mA (472)

DAP values vary from unit to unit in relation to the x-ray tube output. Thus above values indicate average DAP values. In addition to these recommended values, there is a possibility to use the whole mA range if the user prefers.

Available mA ranges for each field of view sizes and resolution settings							
Resolution	**FOV (h x w)**	**4 mA**	**5 mA**	**6.3 mA**	**8 mA**	**10 mA**	**13 mA**
Endo program	61 x 41 mm	x	x	x	x	x	x
High Res	61 x 41 mm	x	x	x	x	x	x
Std Res	61 x 41 mm			x	x	x	x
High Res	61 x 78 mm	x	x	x	x	x	
Std Res	61 x 78 mm			x	x	x	x

Exposure settings for scout imaging (default values)				
Resolution	**FOV (h x w)**	**kV**	**mA**	**Scan-ning time**
Scout	61 x 41 mm	90	13	0,02 s
Scout	61 x 78 mm	90	13	0,04 s

3.4.1 SMAR™, SOREDEX® Metal Artifact Reduction

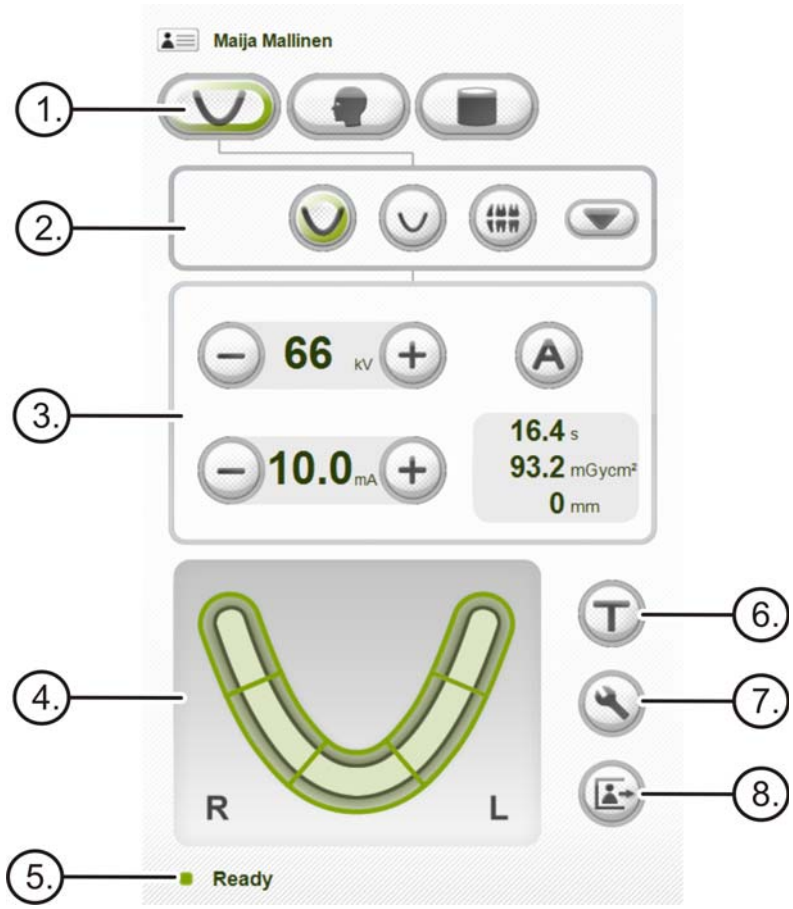
SMAR™, SOREDEX® Metal Artifact Reduction software can be used to reduce the effect of metals and other dense radiopaque objects on the 3D image. These create artifacts that are seen typically as stripes and shadows from the above-mentioned objects. To utilize SMAR™ on a 3D image may have affect to image reconstruction time

SMAR™-button is ON. SMAR™-button becomes visible on the 3D modality.

SMAR™-button is OFF.

4 Controlling the unit

4.1 ClearTouch™ control panel



1. Modality selection
2. Program selection
3. Imaging values
4. Imaging area
5. Status of the unit
6. Test mode
7. Settings
8. Case end

4.2 Modality section

Select the modality button PAN, CEPH or 3D.

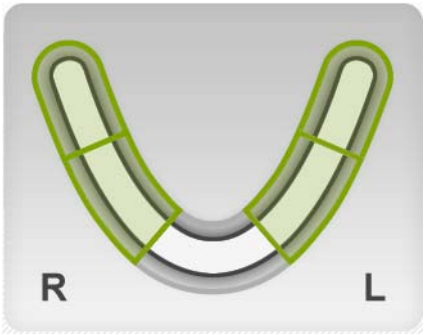
When panoramic modality is selected, a program specific dental arch is shown. This can be used for partial panoramic imaging.

Cephalometric programs have their own, program specific model heads and setting buttons for the start position of lateral scanning.

3D programs (two FOV sizes) have buttons for selecting low resolution, high resolution or scout image mode. The FOV for 3D imaging can be positioned on the XY-plane by selecting the center point of the FOV on the dental arch of the touch screen display. The FOV is positioned in the Z-direction by using the chin rest movement and positioning lights.

4.3 Sectional imaging

Dental arch on the touch panel shows the enabled and disabled arch sections from the result point of view. Select the image area from the dental arch.



4.4 Automatic Exposure setting (AES)

AES automatically recommends the exposure values according to the size of the patient's head in panoramic and cephalometric imaging. The AES is activated with active A button and by pushing Return button once. The AES suggest exposure values based on patient size. The user can change the value before exposure if needed by pushing **A** button again and changing the values.

4.4.1 AES values for Panoramic imaging

Note! *Values can be re-scaled by SOREDEX authorized service personnel.*

Adult, child panoramic, Bitewing, Sinus		
Head width (min)	**kV**	**mA**
19,3 cm (Max)	70	13
15,9 cm	70	10
14,2 cm	70	8
13,35 cm	66	8
12,925 cm	66	6,3
12,5 cm (Min)	66	5

AES values for TMJ Lat/PA		
Head width (min)	**kV**	**mA**
19,3 cm (Max)	73	16
15,9 cm	73	13
14,2 cm	73	10
13,35 cm	73	8
12,925 cm	73	6,3
12,5 cm (Min)	73	5

4.4.2 AES values for Cephalometric imaging

Lat/PA 100 V			
Head width (min)	**kV**	**mA**	**s**
17,3 cm (Max)	90	8	20
14,45 cm	90	8	20
12,65 cm	90	8	16
11,45 cm	90	8	12,5
10,55 cm	90	8	10
6,5 cm (Min)	85	8	10

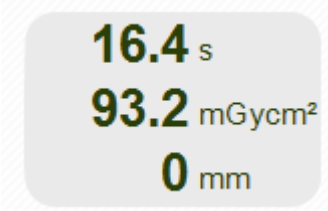
Ceph Lat/PA 120 V			
Head width (min)	**kV**	**mA**	**s**
17,3 cm (Max)	90	10	20
14,45 cm	90	10	20
12,65 cm	90	10	16
11,45 cm	90	10	12,5
10,55 cm	90	10	10
6,5 cm (Min)	85	8	10

Ceph Lat/PA 240 V			
Head width (min)	**kV**	**mA**	**s**
17,3 cm (Max)	90	12,6	16
14,45 cm	85	12,6	16
12,65 cm	85	12,6	12,5
11,45 cm	85	12,6	10
10,55 cm	85	10	10
6,5 cm (Min)	85	8	10

4.4.3 Exposure indicators and settings

kV value

mA value



Exposure time (s)

Dose value (mGycm^2)

Focal through light (mm)

Focal through light
y-layer position

Test mode

Automatic Exposure setting
(AES)

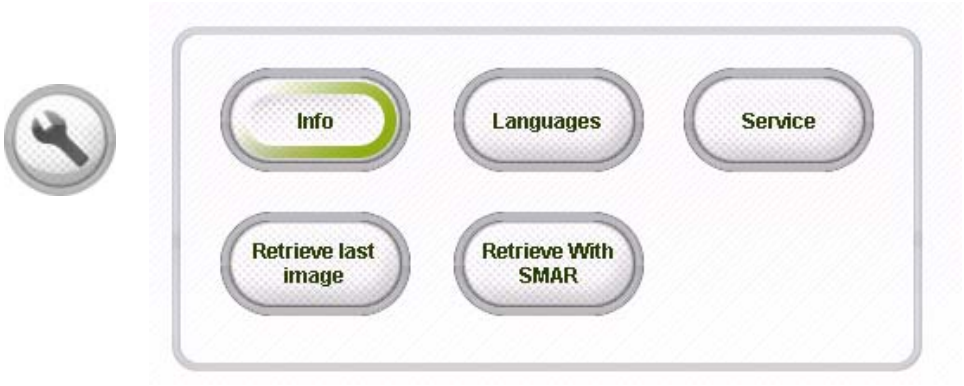
4.5 Status section

Status field shows when the unit is ready for capturing or any trouble occurs. Green or red color indicate the status in question. Green means ready to capture and red means not ready. During actual exposure, a large radiation warning symbol will fill the display area.

Ready for imaging

4.6 Other sections

General settings



- Info
  - System IP address and other system related data
- Languages
  - Use this to select language on the touchscreen
- Service
  - Use this to reach the programs for periodical maintenance
- Retrieve Last Image
  - Use this to retrieve the last image from the device memory e.g. after a system crash
  - Please make sure that the retrieved image is associated with the correct patient
- Retrieve With SMAR™
  - After taking a 3D image with SMAR™ either on or off, image can be re-reconstructed with different setting by selecting either “Retrieve last image” or “Retrieve With SMAR™” from the general settings on the touch screen. If reconstruction with SMAR™ is unavailable for the last captured image, e.g. last taken image is cephalometric, “Retrieve With SMAR™”-button will not be visible.

  NOTE! *Only the last taken x-ray image is saved in the unit until the power is switched off. This image data is used in the retrieve procedure.*

5 Using the unit

5.1 Attaching and removing the sensor

Note! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

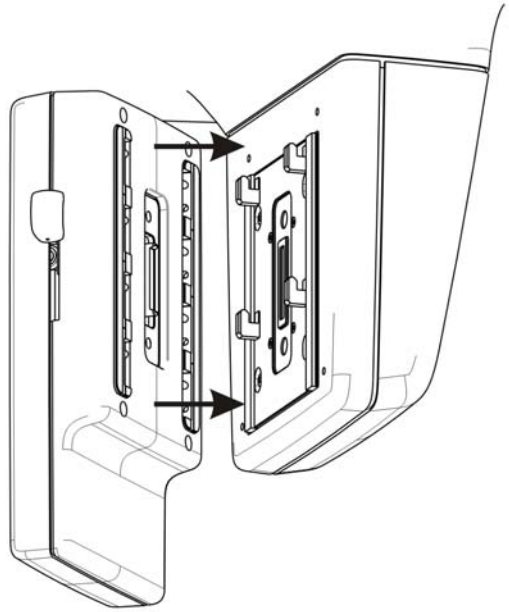
Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.

WARNING!

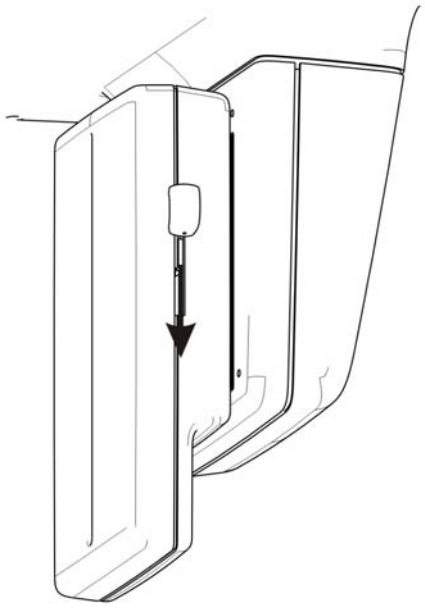
Handle the sensor with care as instructed in this manual. The sensor must not be dropped or exposed to impacts. A shock indicator inside the sensor shows if the sensor has been exposed to excess impact.

5.1.1 Attaching the sensor

1. Insert the four slots on the rear of the sensor, into the four hooks in the sensor holder.

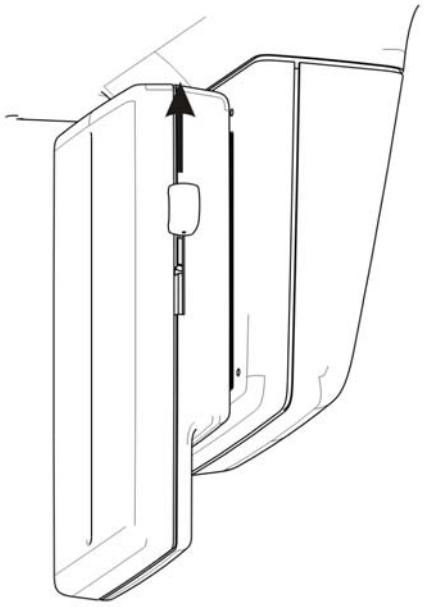


2. Slide the sensor downwards until it stops and then slide the locking knob down on the side of the sensor to lock the sensor in position.



5.1.2 Removing the sensor

1. Slide the locking knob upwards on the side of the sensor to unlock the sensor.



2. Slide the sensor up and remove it.

5.2 Preparing the system

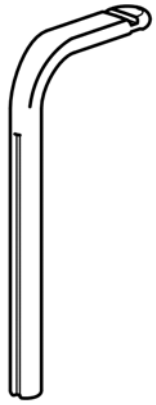
1. Switch on the unit and the PC.
2. **PC:** Start SCANORA® software (or 3rd party application).
3. **PC:** Open a new or existing patient or select a patient from the worklist. See the user's guide supplied with the dental imaging program.

5.3 Panoramic exposures

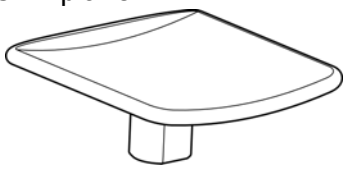
- Adult panoramic
- Child panoramic (Reduced width and height)
- Bitewing
- Maxillary sinus
- TMJ, PA/AP projection
- TMJ, lateral projection (axially corrected)

5.3.1 Positioning devices

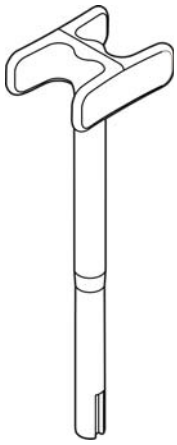
Bite block



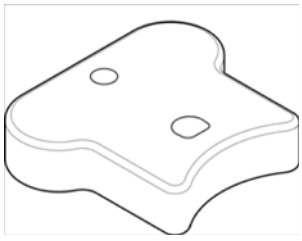
Chin plane



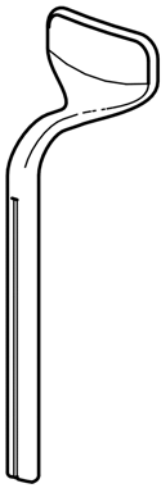
TMJ support



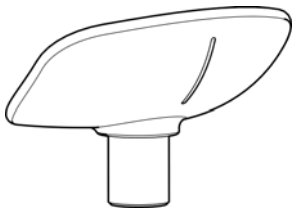
Chin rest holder



Lip holder for edentulous patients

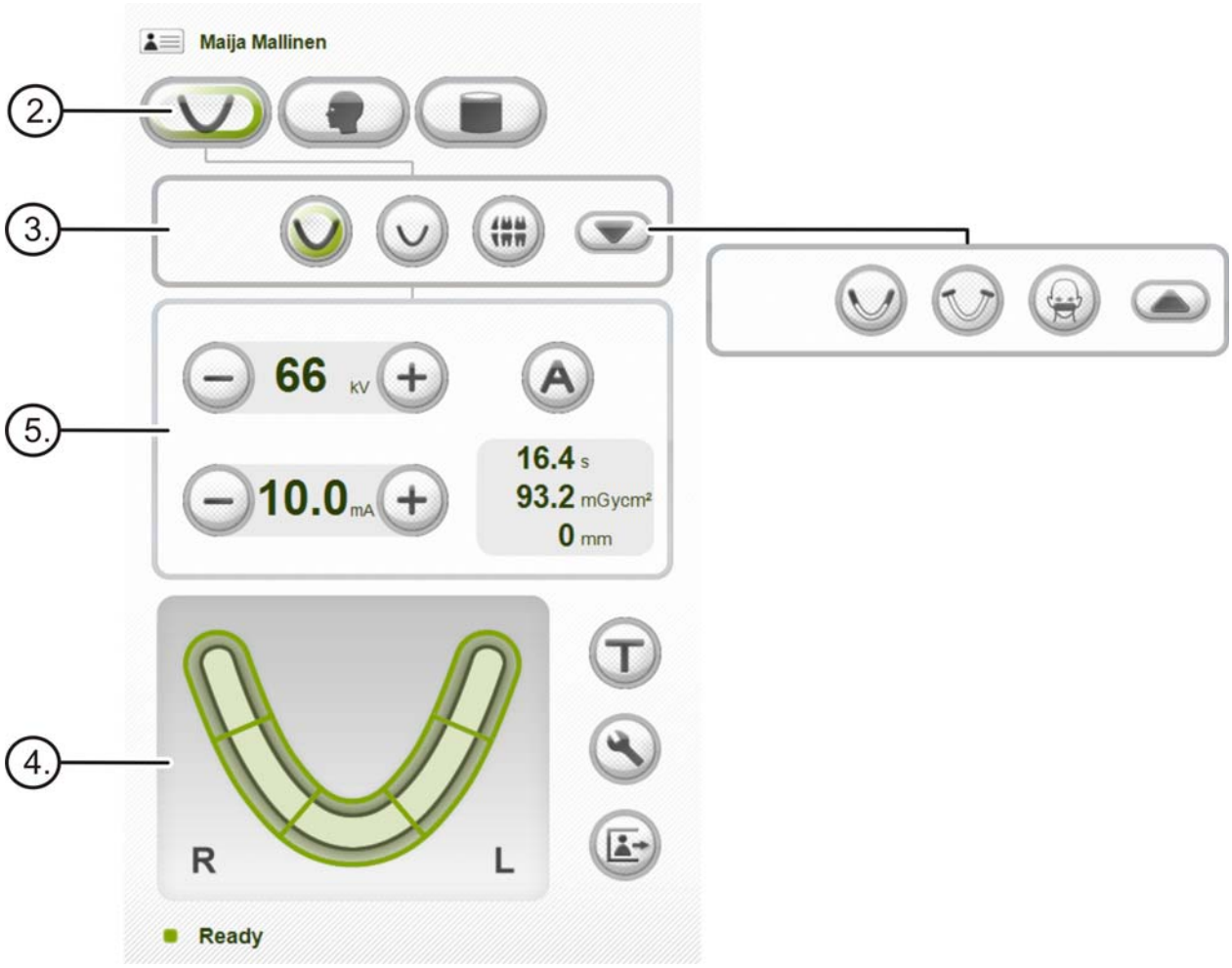


Chin cup



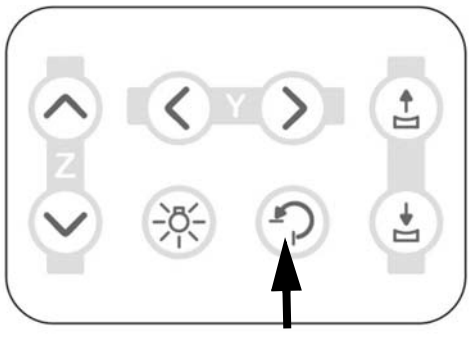
5.3.2 General instructions

1. **PC**: Click **Image Capture**.



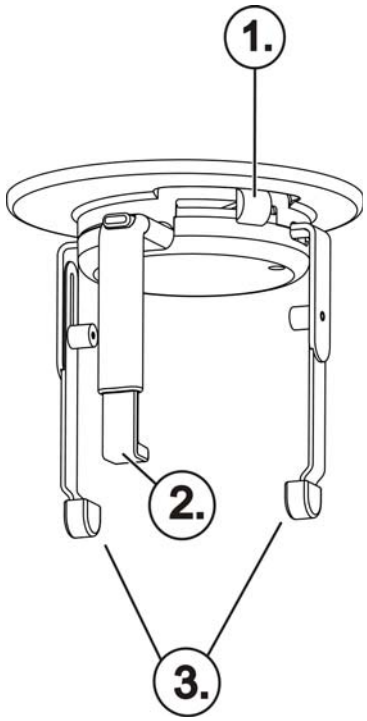
2. Select panoramic imaging.
3. Select the imaging program.
4. Any section of the dental arc can be selected for the sectional imaging to limit exposure area and reduce the radiation dosage.

5. Press the Return button to rotate the unit to ‘patient in’ position.



6. Open the temple supports.

   1 Temple support knob
   2 Forehead support
   3 Temple supports



7. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins. Place a protective lead apron on the patient.

5.3.3 Patient positioning

5.3.3.1 Panoramic exposure

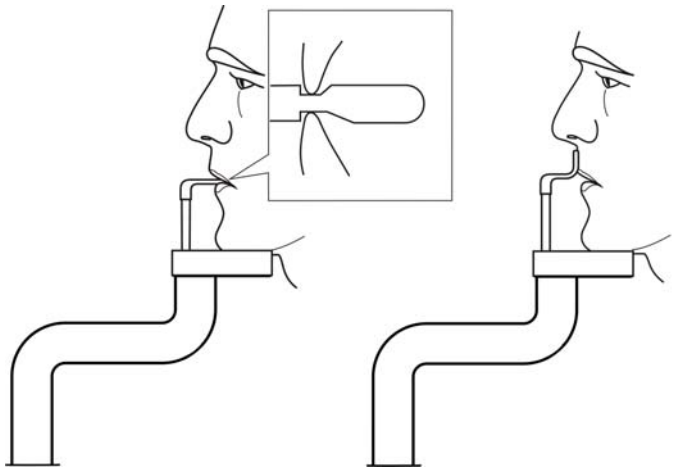
1. Insert the chin rest and bite rod with the bite block. Place the disposable covers.

   Note! *Use a new disposable cover for every patient.*

2. Adjust the unit height.

3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Exposure can be taken also in sitting position. Ask the patient to take grip on the handles and bite on the bite block. Use the lipholder or the chin support for an edentulous patient.

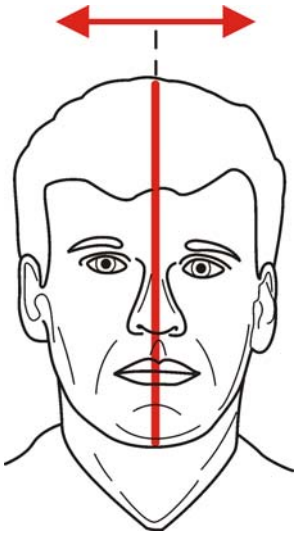
Figure 1.1 bite block and lip holder

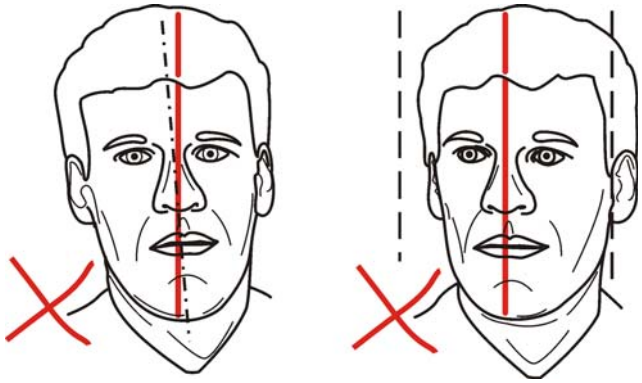


4. Ask the patient to take one step forward to straighten the spinal column. Patient is slightly leaning backwards during the imaging.

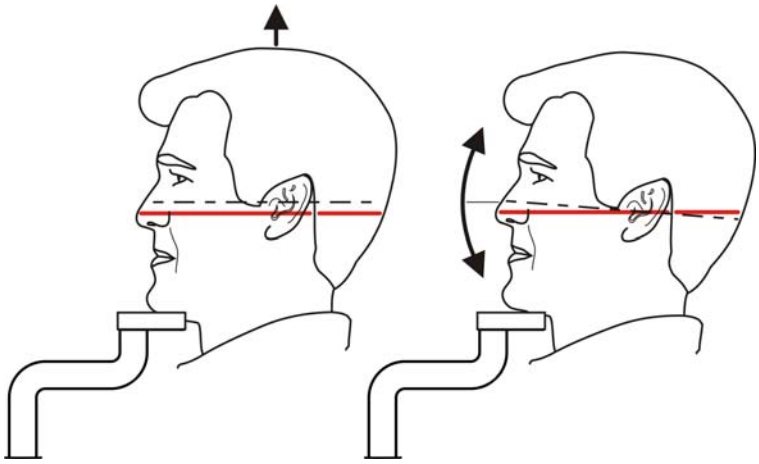
5. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.

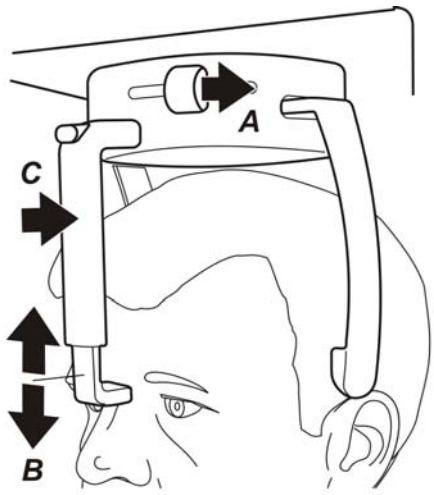
   Make sure the patient's head is not turned or tilted.





6. Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.

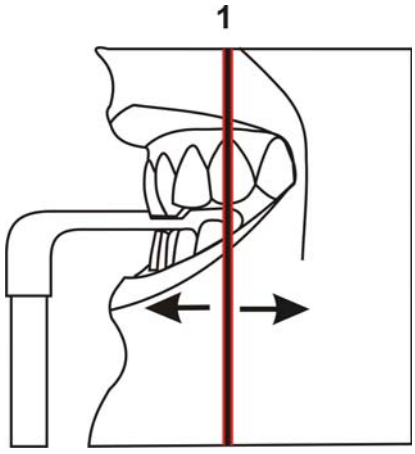




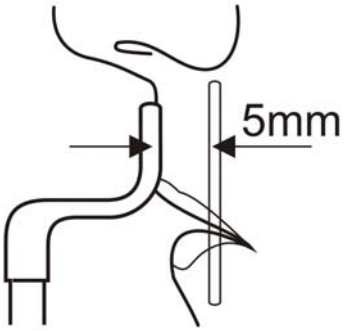
7. Close the temple supports by sliding the temple support knob to the right (A). Adjust the position of the nasion support (B) and push the forehead support in until it touches the patient's nasion (C).

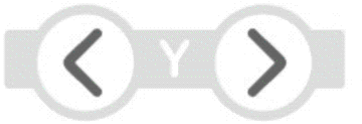
8. The focal trough light indicates the center of the focal trough, which is 10 mm wide at the front. The root apices of the patient's central upper and lower front incisors must be within the focal trough.

   Ask the patient to open their lips so that you can see their teeth. The focal trough light should be positioned slightly in front of the root apices, which for most patients will be in the middle of 3rd tooth (canine).



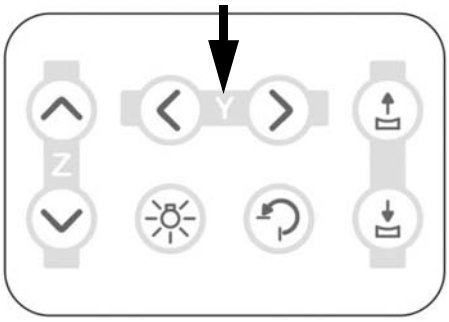
If the patient is edentulous the focal trough light should be approximately 5mm behind the lip holder when the focal trough position is 0 mm.



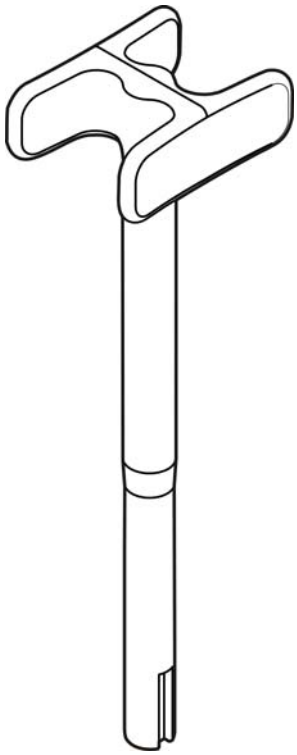


Note! *If the focal trough light is not positioned as described above, press the focal trough adjustment key(s) to move the focal trough light until it is positioned correctly.*

Figure 1.2 Focal trough light position indicator



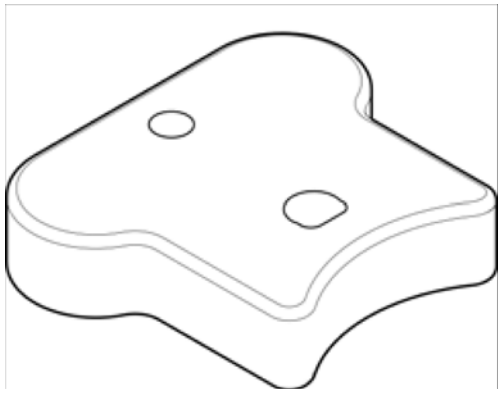
9. If AES is enabled (green light lit around "A"), press the Return button and wait for the movement to finish. Verify that the suggested exposure values are suitable for the patient. If AES is disabled, set the exposure values manually and press Return to drive the unit into exposure start position (optional).
10. Ask the patient to press their tongue against the roof of their mouth, **swallow** and remain still for the duration of the exposure.



5.3.3.2 TMJ exposure

1. Insert the required positioning devices, including the TMJ support. Place the disposable covers.

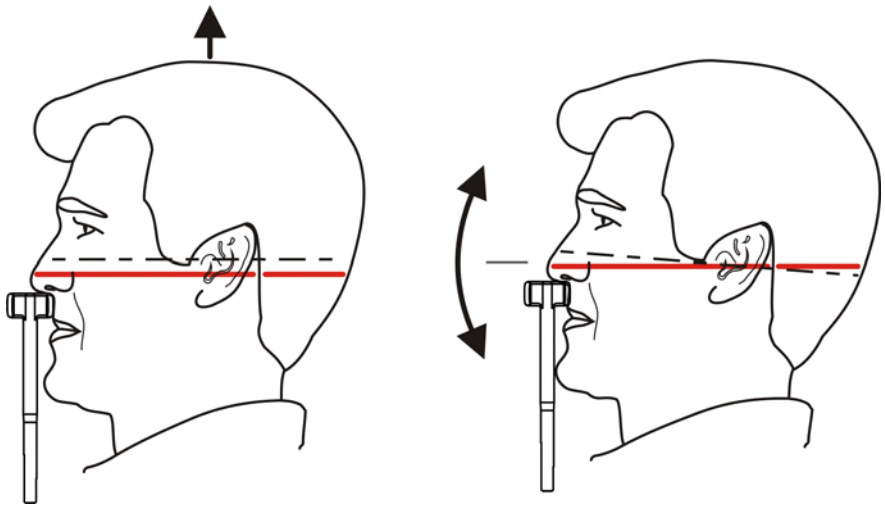
Note! Use a new disposable cover for every patient.



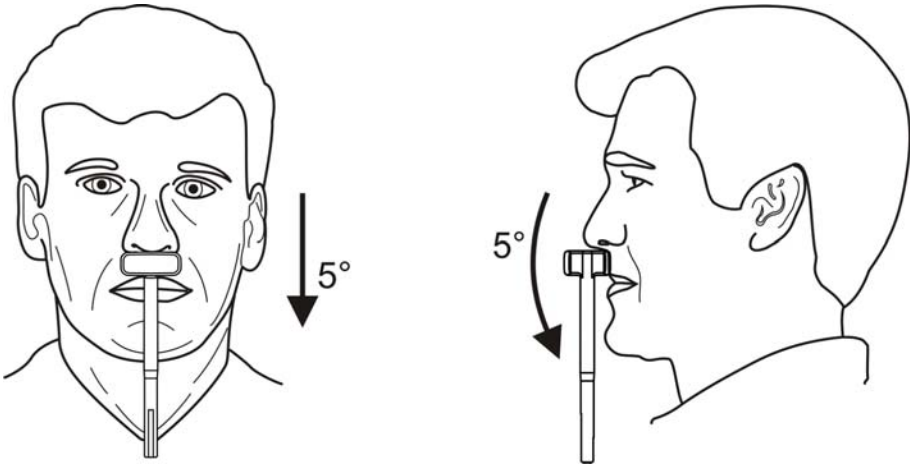
2. Adjust the unit height.

3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Ask the patient to take grip on the handles and set the mouth against the lip holder.

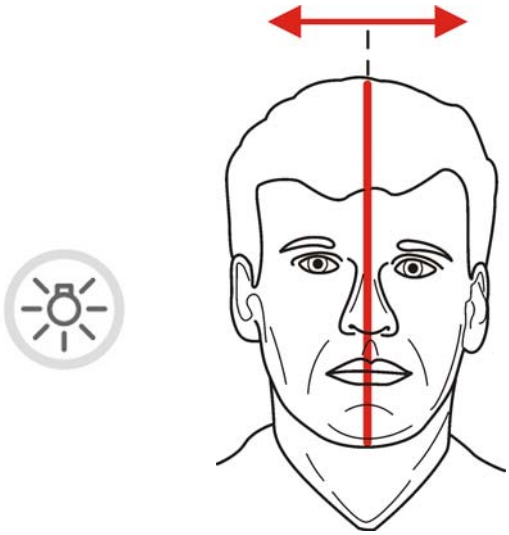
4. TMJ lateral projection: Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.



5. TMJ PA/AP projection: Tilt the patient's head forward.



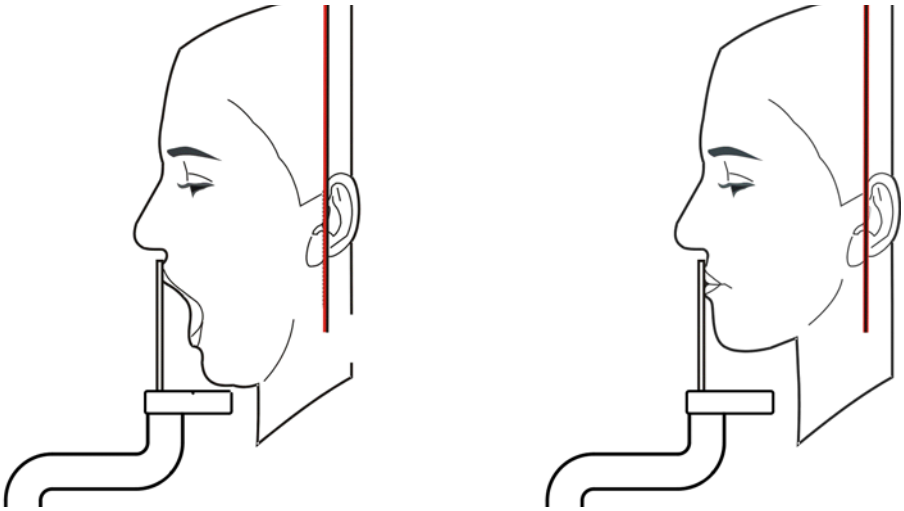
6. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.



7. Close the temple supports by sliding the temple support knob to the right. Adjust the position of the nasion support and push the forehead support in until it touches the patient's nasion.

8. Adjust the position of the TMJ light until it aligns in the middle of condyle.

   Note! *The condyle moves forward by approximately 10 mm when the mouth is opened"*



9. If AES is enabled (green light lit around "A"), press the Return button and wait for the movement to finish. Verify that the suggested exposure values are suitable for the patient. If AES is disabled, set the exposure values manually and press Return to drive the unit into exposure start position (optional).

10. Ask the patient to press their tongue against the roof of their mouth, swallow and remain still for the duration of the exposure.

5.3.3.3 Maxillary Sinus exposure

1. Insert the the lip holder for sinus imaging.
   Place the disposable covers.

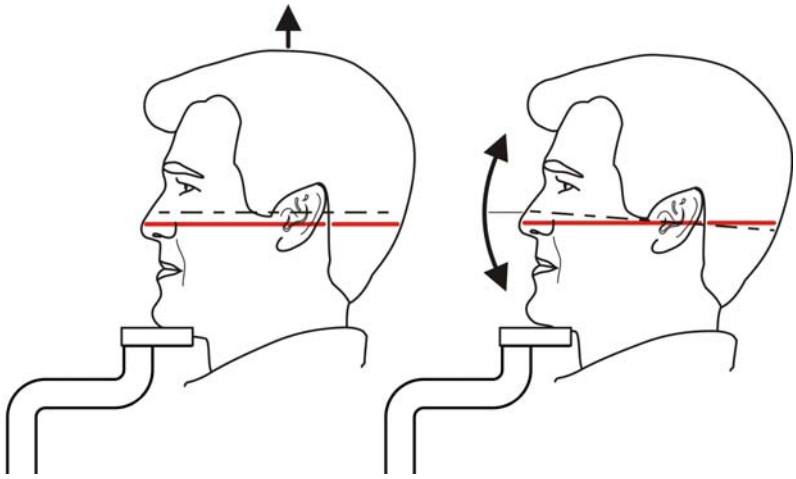
Note! *Use a new disposable cover for every patient.*

2. Adjust the unit height.

3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Ask the patient to take grip on the handles and set the mouth against lip holder.

4. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.

5. Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.



6. Close the temple supports by sliding the temple support knob to the right. Adjust the position of the nasion support and push the forehead support in until it touches the patient's nasion.

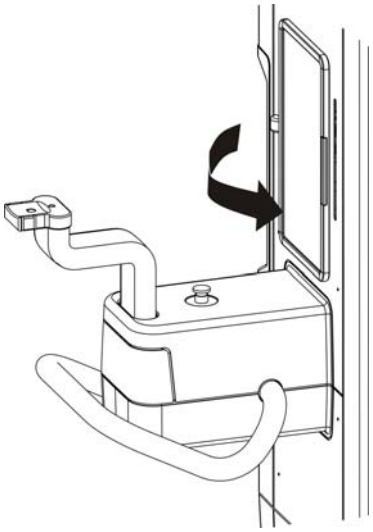
7. Adjust the position of the image layer as necessary. The focal trough light should be positioned in the middle of the 3rd tooth or if wanted slightly posterior.

Note! *If the focal trough light is not positioned as described above, press the focal trough adjustment key(s) to move the focal trough light until it is positioned correctly.*

8. If AES is enabled (green light lit around "A"), press the Return button and wait for the movement to finish. Verify that the suggested exposure values are suitable for the patient. If AES is disabled, set the exposure values manually and press Return to drive the unit into exposure start position (optional).

9. Ask the patient to press their tongue against the roof of their mouth and remain still for the duration of the exposure.

5.3.3.4 Taking the exposure



WARNING!

Close the patient positioning mirror before taking any exposures.

1. Ask the patient to remove any spectacles, dentures, jewellery and hair clips and pins. Place a protective lead apron around the patient's neck to protect the patient's thyroid gland from radiation.

2. Press **Return**. Check the patient positioning.

   Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.

Note! *In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray beam. Operator should maintain visible contact with the patient and Technical factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.*

Note! *If the patient is nervous, or a child, you can demonstrate how the unit works to reassure them. Press the T (Test mode) button and then press and hold the exposure button. The unit will complete an exposure cycle without generating x-rays.*

3. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the ClearTouch™ control panel appears.
   The unit rotates around the patient's head and stops. When the rotating unit stops, the exposure has been taken.
4. After the exposure the rotating unit is in 'patient out' position, if the exposure switch has been pressed until all movements have stopped. Release temple supports. Guide the patient out. Remove disposable covers and disinfect the unit.
5. **PC:** The image can be examined using the SCANORA® software. See SCANORA® software user's manual.

5.4 Cephalometric exposures

- Reduced Width lateral projection
- Lateral projections
- PA/AP projection
- Reverse towne projection
- Waters view
- Carpus program (optional)
  (Not available in USA and Canada)

WARNING!

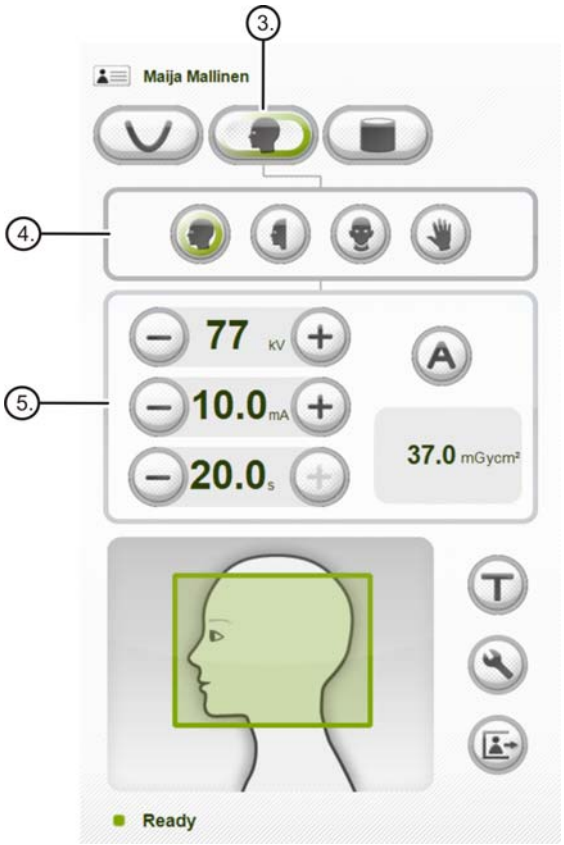
Remove all calibration tools, Pan and 3D patient positioning accessories before taking any cephalomateric exposures!

5.4.1 General instructions

1. Move the ceph sensor to the ceph sensor holder in a case of single sensor configuration.

2. **PC:** Click **Image Capture**.

3. Select CEPH.



4. Select the imaging program.

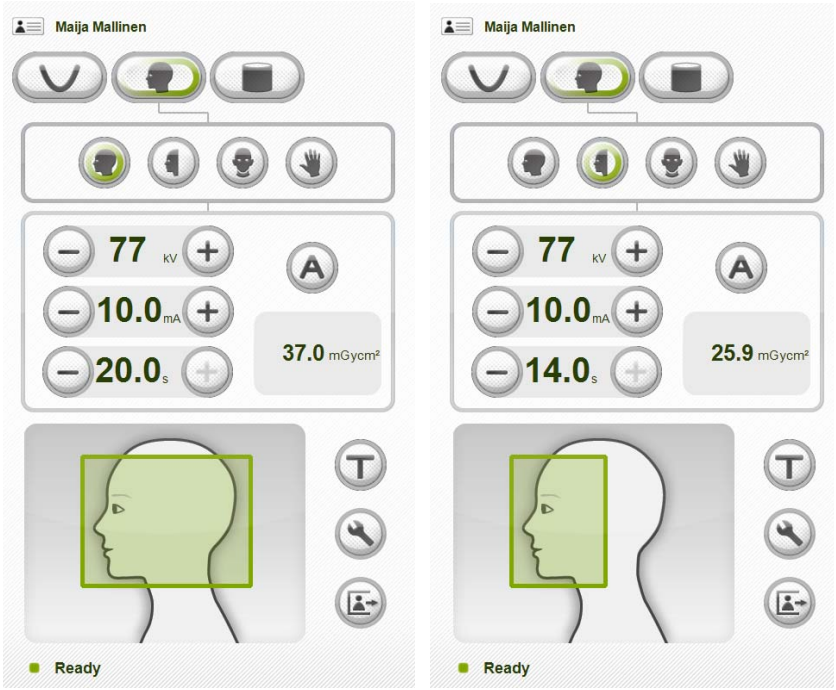
5. If AES is enabled (green light lit around "A"), press the Return button and wait for the movement to finish. Verify that the suggested exposure values are suitable for the patient. If AES is disabled, set the exposure values manually and press Return to drive the unit into exposure start position (optional).

6. Press **Return** to drive the unit to '*patient in*' position.

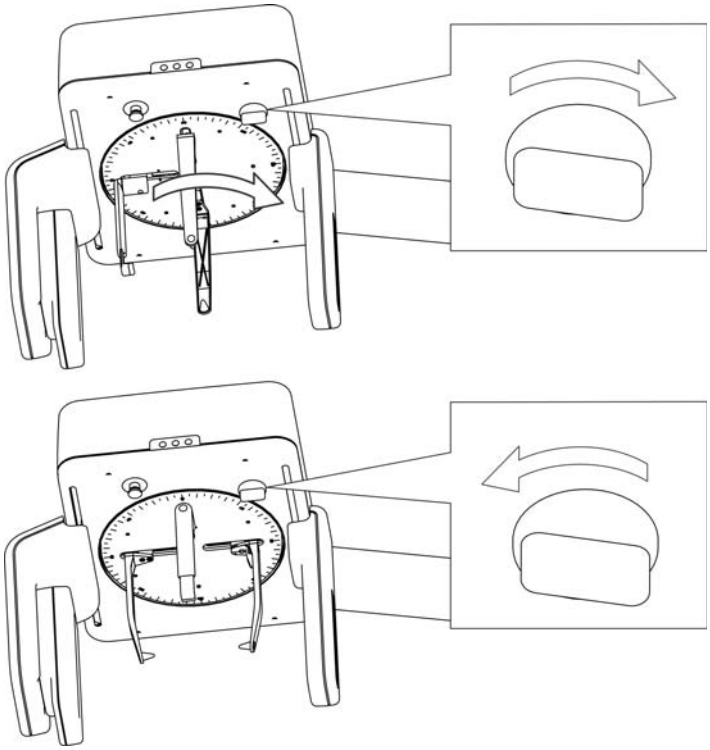
7. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewelry and hair clips and pins. Place a protective lead apron on the patient.

5.4.2 Patient positioning

5.4.2.1 Full width and reduced width projection



1. Unlock the lever and turn the ear rods to the lateral projection position. Lock the position.



2. Place the disposable covers.

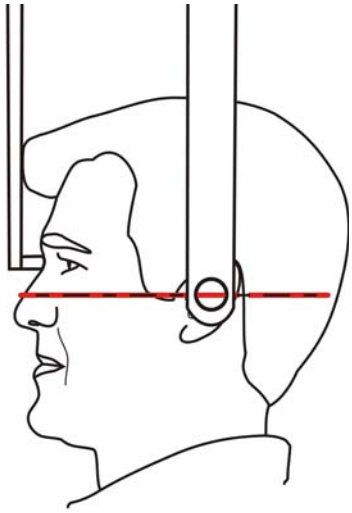
   Note! *Use a new disposable cover for every patient.*

3. Adjust the unit height.

4. Guide the patient to the unit. Instruct the patient to stand as straight and tall as possible under the cephalostat head. Slide the ear rods towards to patient's ears. Tall patients can also sit on a chair.

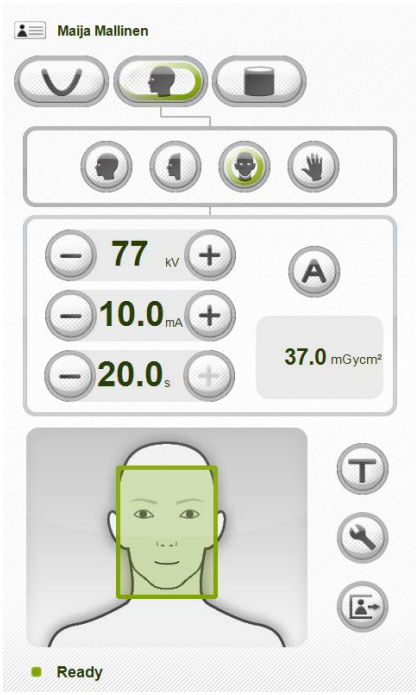
5. Adjust the patient head so that the Frankfort-Horizontal plane (FH) and laser light are in same horizontal plane.

Note!
The shown laser line is a horizontal reference line.

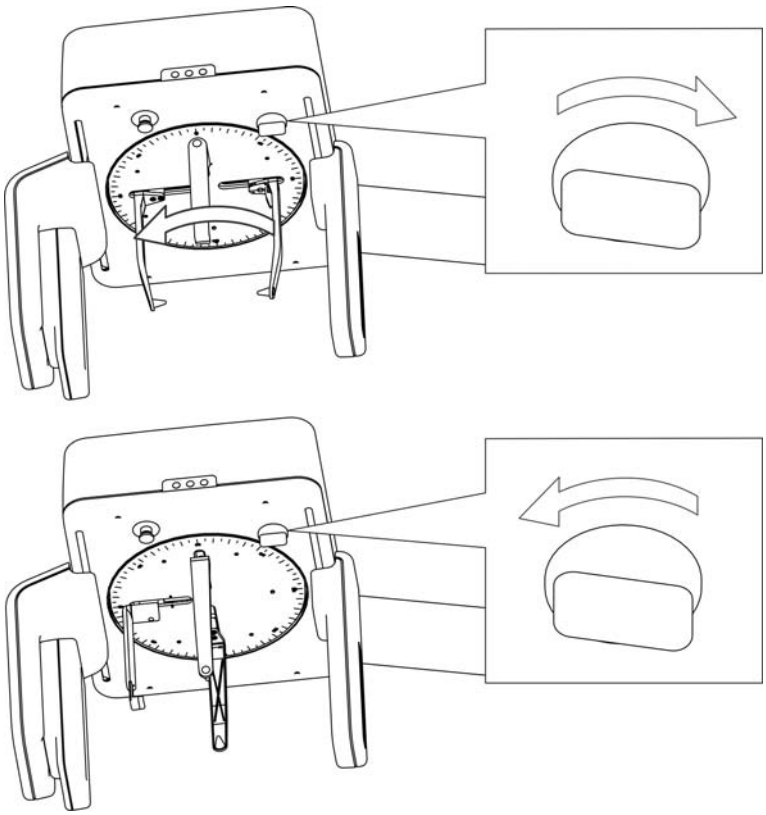


6. Slide nasion support against patient’s nasion.

5.4.2.2 PA projection



1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside.



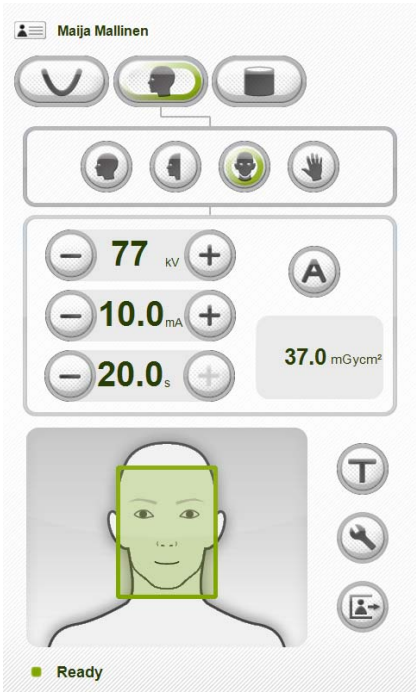
2. Place the disposable covers.

   Note! *Use a new disposable cover for every patient.*

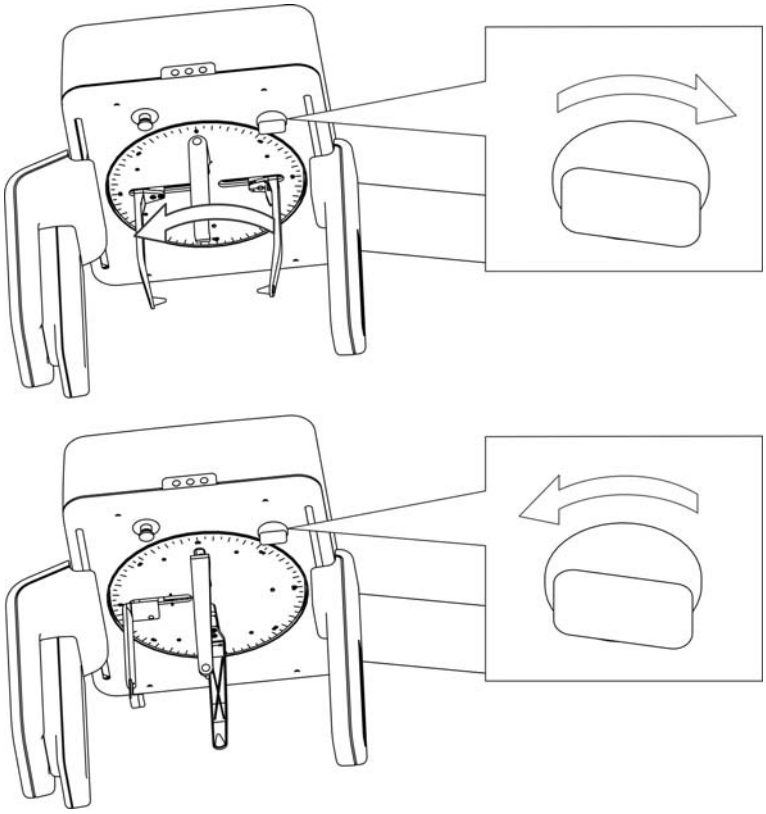
3. Adjust the unit height.

4. Guide the patient to the unit facing the sensor. Instruct the patient to stand as straight and tall as possible under the cephalostat head. Slide the ear rods towards patient's ears. Tall patients can also sit on a chair.

5.4.2.3 Reverse towne projection



1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside.



2. Place the disposable covers.

Note! *Use a new disposable cover for every patient.*

3. Adjust the unit height.

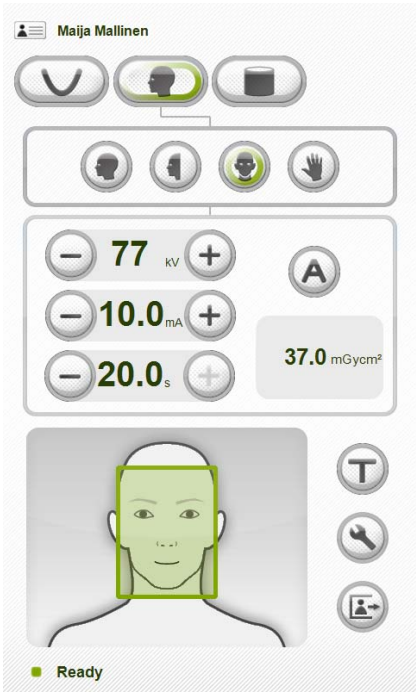
4. Guide the patient to the unit facing the sensor. Instruct the patient to stand as straight and tall as possible under the cephalostat head.

5. Turn the head ventral as reference to the canthomeatal line about 30° below the horizontal plane.

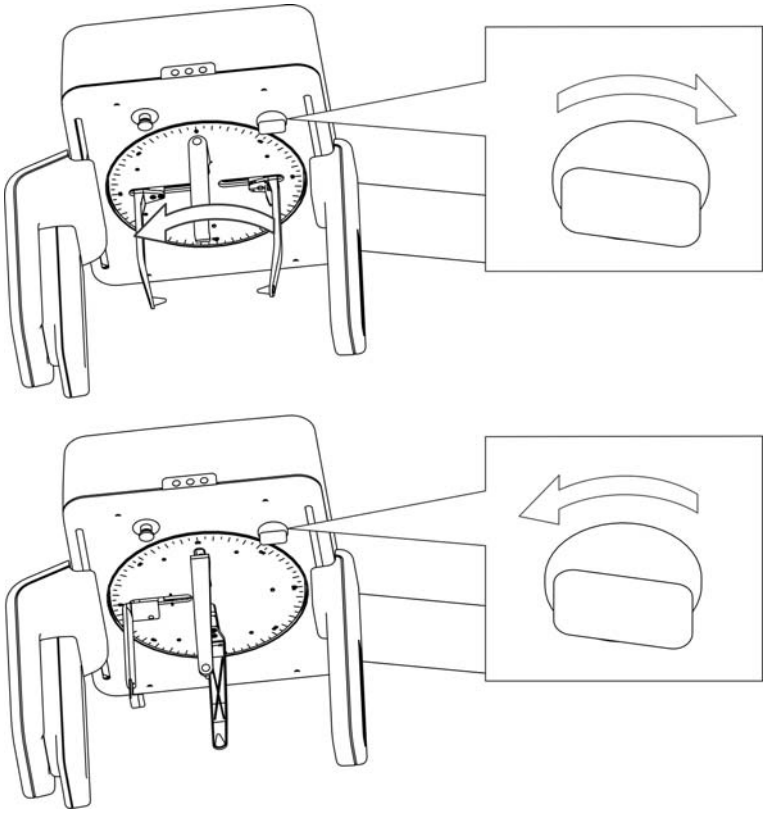
6. Slide the ear rods towards patient's ears.

7. Ask the patient open mouth maximally.

5.4.2.4 Waters view



1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside.



2. Place the disposable covers.

Note! *Use a new disposable cover for every patient.*

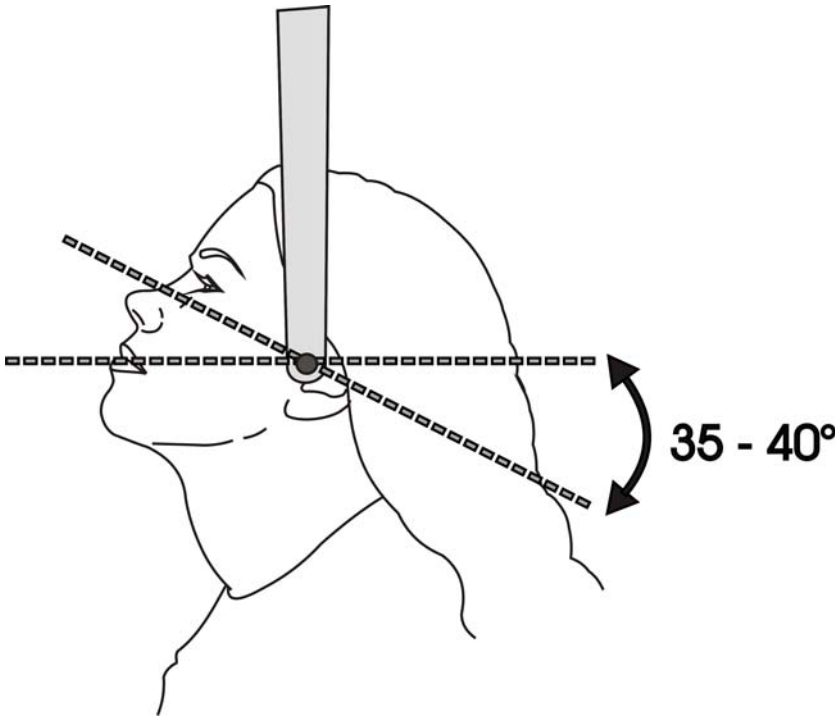
3. Adjust the unit height.

4. Guide the patient to the unit facing the sensor. Instruct the patient to stand as straight and tall as possible under the cephalostat head.

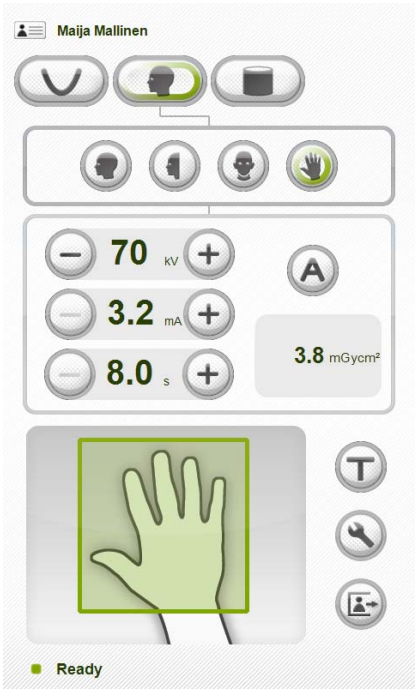
5. Turn the head torsal as reference to the canthomeatal line about 35-40° above the horizontal plane.

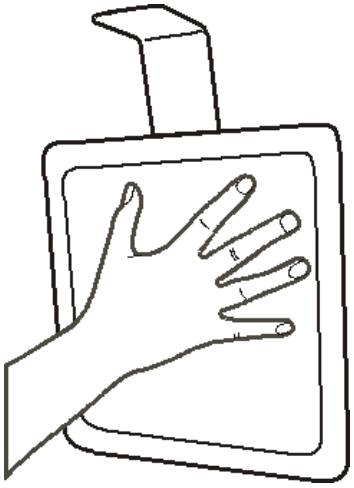
6. Slide the ear rods towards patient's ears.

7. Ask the patient open or close mouth.



5.4.2.5 Carpus program (optional) (Not available in USA and Canada)





CAUTION!

Before taking Carpus image make sure this imaging method is approved by local authorities of your country.

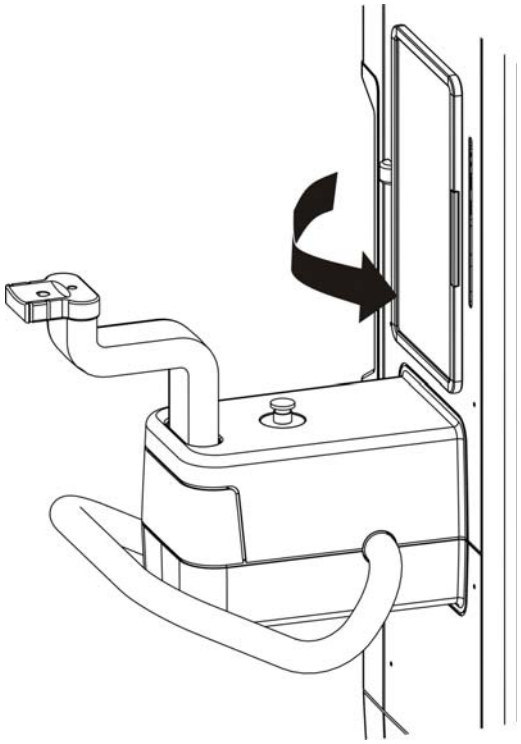
1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside. Place the carpus holder to the nasion support holder.
2. Adjust the unit height if needed.
3. Ask the patient to remove rings and metal objects and to place hand on the carpus holder.

Note! *Carpus holder is a separate accessory. Order from local distributor.*

5.4.2.6 Taking the exposure

WARNING!

Close the patient positioning mirror before taking any exposures.



1. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins. Place a protective lead apron around the patient's neck to protect the patient's thyroid gland from radiation.

2. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.

3. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the ClearTouch™ control panel appears.

4. Release the ear rods and guide the patient out.
Remove disposable covers and decontaminate the unit.

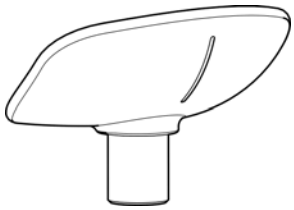
5. **PC:** The image can be examined using the SCANORA® software. See SCANORA® user manual.

Note! *In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray beam. Operator should maintain visible contact with the patient and technique factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.*

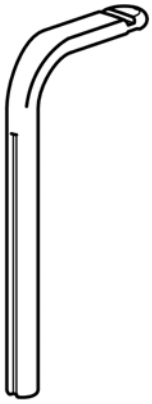
5.5 3D exposures

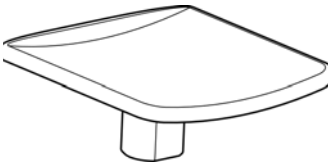
5.5.1 Positioning devices

Chin cup



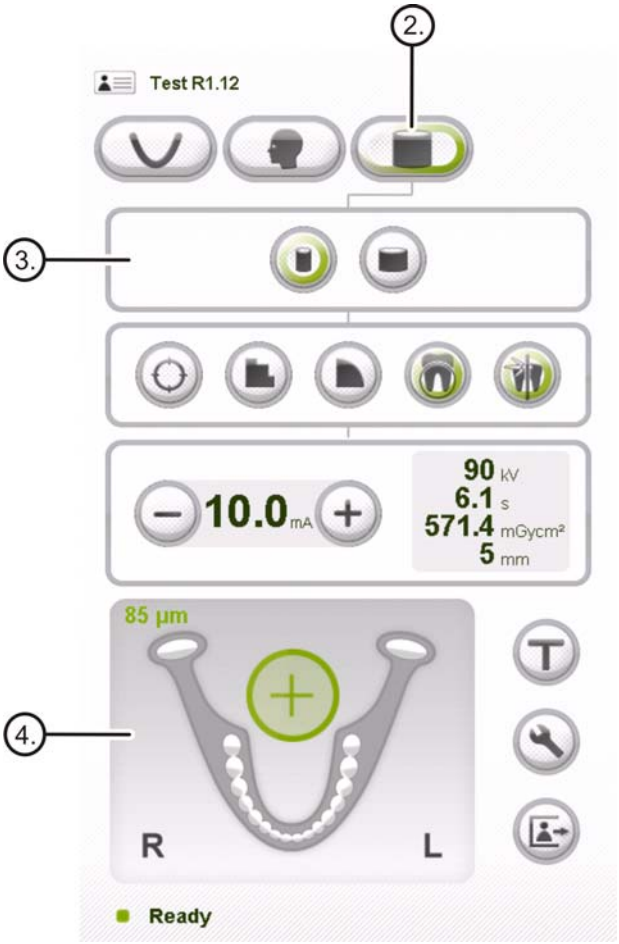
Bite block and chin plane





5.5.2 General instructions

1. PC: Click **Image Capture**.
2. Select the 3D modality.



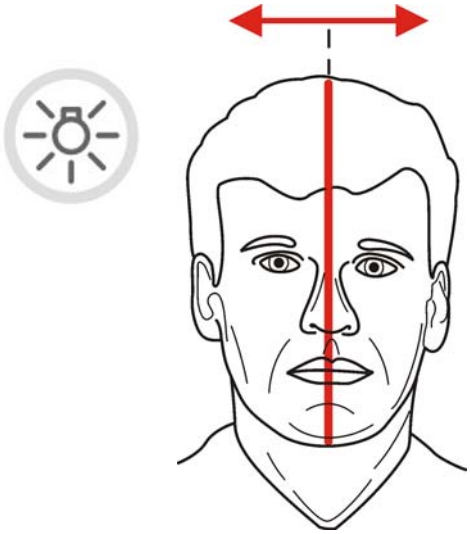
The teeth locations on the 3D dental arch are approximate and are based on average dentition. The exact teeth locations will depend on the patient's individual anatomy.

The EasyScout function helps locate the correct dental location of the Field of view.

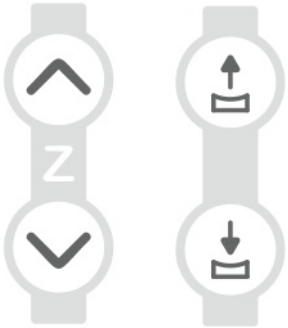
3. Select the Field Of View (FOV):
   XS FOV 61 x 41 mm (Program 1)
   Endo program FOV 61 x 51 mm
   Midi FOV 61 x 78 mm (Program 2) (OPTIONAL)
4. Select the area of interest on the dental arch. The 3D FOV is positioned more accurately by using the scout image mode. The area of interest can be adjusted on the ClearTouch™ control panel after the scout image has been taken.
5. Press **Return** to rotate the unit to 'patient in' position.

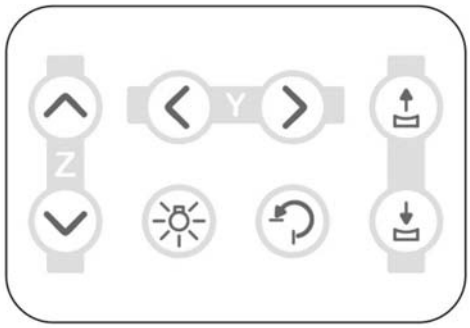
6. Adjust the unit height.

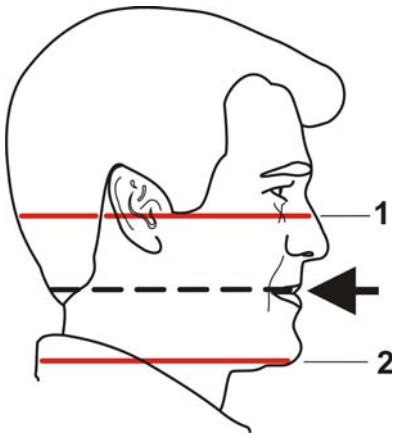
7. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins.
8. Guide patient to the unit. Instruct patient to stand as straight and tall as possible next to the unit. Patient can also be imaged in sitting position. Ask the patient to take grip on the handles and place chin on the chin cup.
9. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.



10. Adjust the unit height and chin rest height to get the area of interest between the top and bottom FOV lights. Position the patient so that the occlusal plane is horizontal.



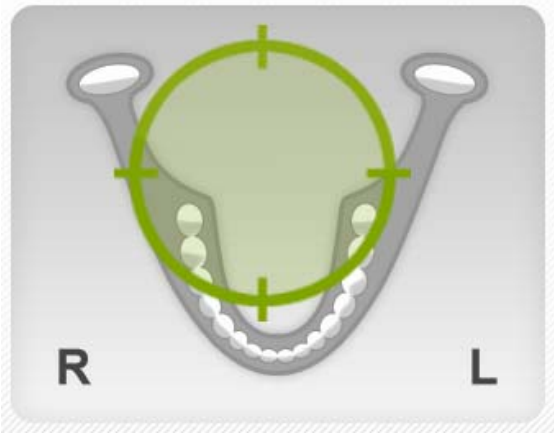




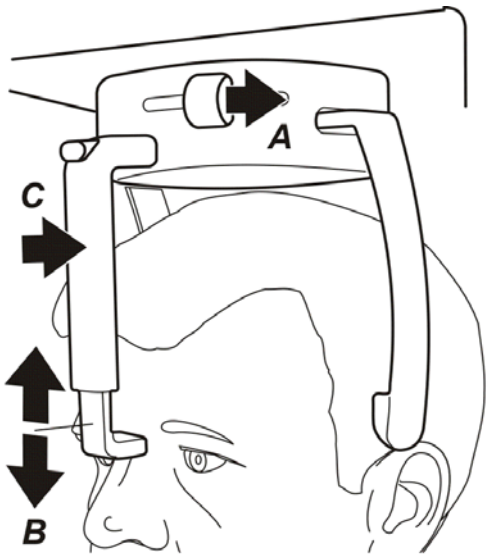
1. Horizontal light, top of FOV
2. Horizontal light, bottom of FOV

Note! *Target ROI is always in the middle plane of laser lights.*

11. Select the image area from the dental arch.



12. Close the temple supports by sliding the temple support knob to the right (A). Adjust the position of the nasion support (B) and push the forehead support in until it touches the patient's nasion (C).

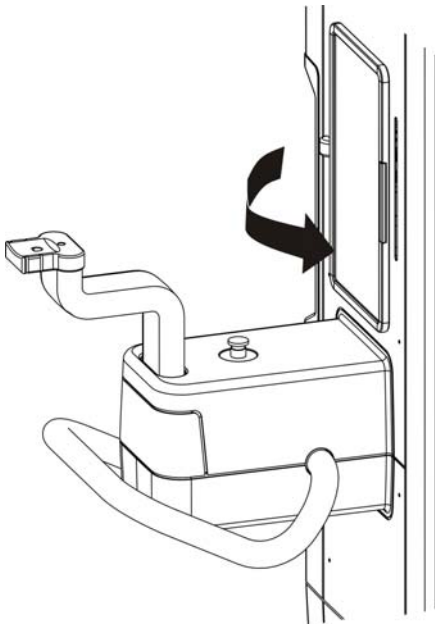


13. Select

A the Scout image
or
B the Standard
or
C High resolution 3D image
or
D Endo program

A **B** **C** **D**

5.5.3 Scout image



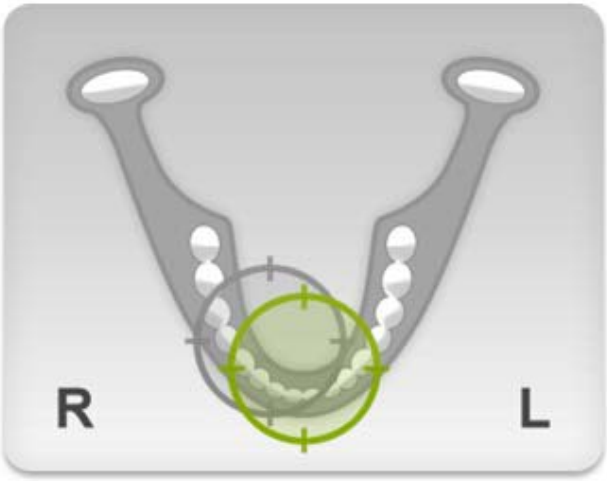
WARNING!

Close the patient positioning mirror before taking any exposures.

1. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the ClearTouch™ control panel appears.

2. Scout preview image appears to the ClearTouch™ control panel.
3. Fine adjust scout position using the side arrow keys. Press the left lower corner icon to continue.

4. Take a new scout or
   save current and continue to 3D image.
5. Previous FOV position is shown as gray circle and new position is showed as green circle.



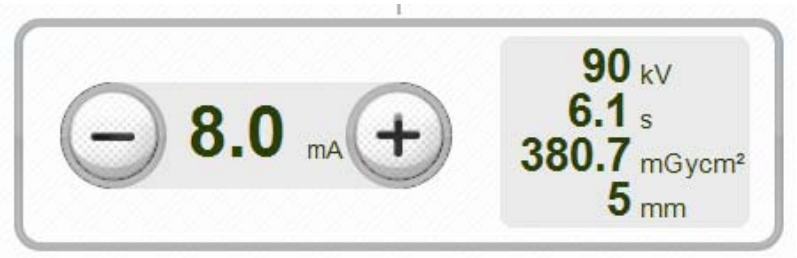
Note! *Gray circles remain in control panel until you change the patient.*

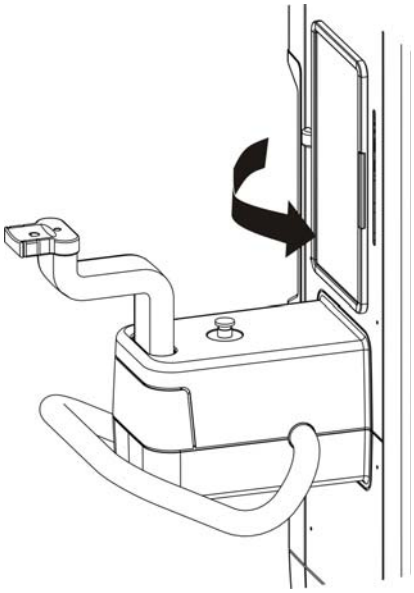
5.5.4 3D image

1. Select the Standard (A), high resolution (B) or endo program (C). Endo program is only for 61 x 41 mm FOV.

A B C

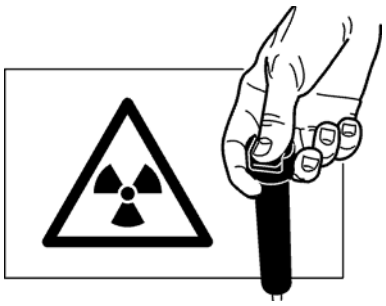
2. Select mA.





WARNING!

Close the patient positioning mirror before taking any exposures.



3. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the ClearTouch™ control panel appears.
4. Select **SMAR™** ON or OFF based on your estimation of the need. See chapter 3.4.1. SMAR™, SOREDEX® Metal Artifact Reduction.

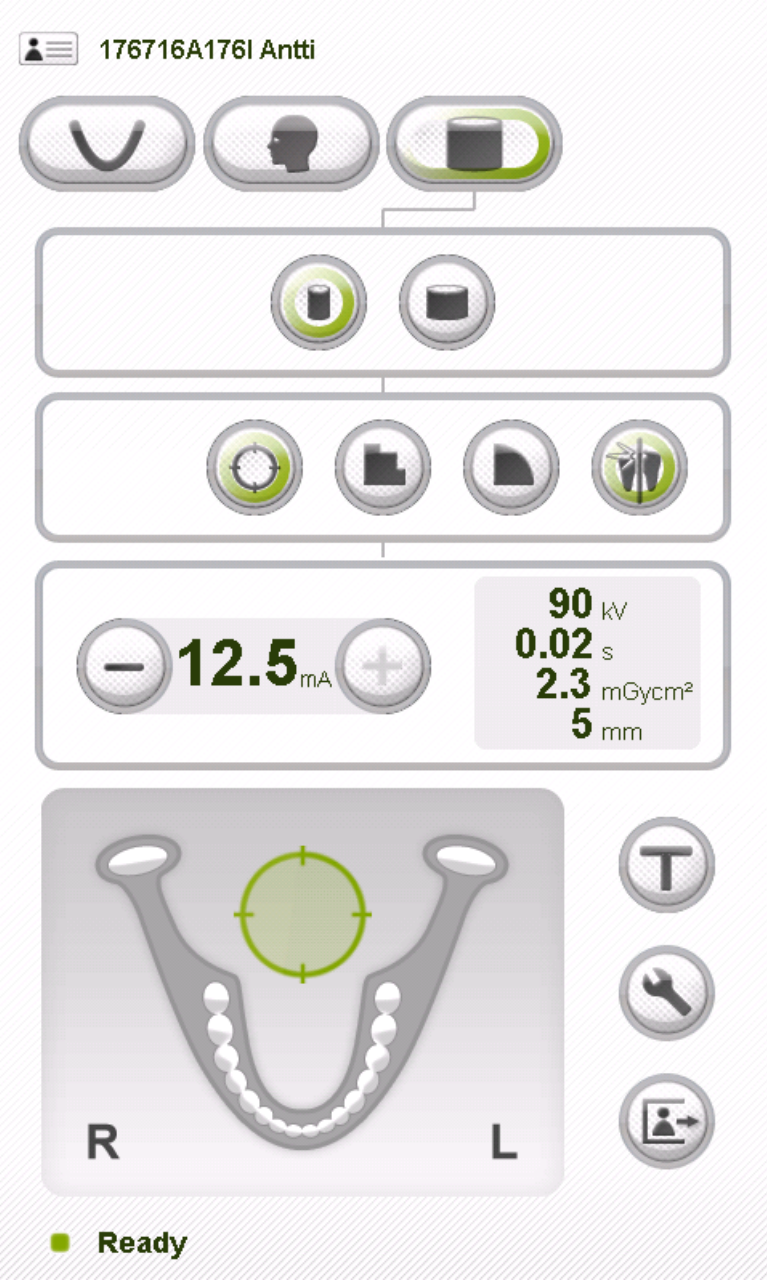
5.5.5 Stone model and radiographic guide scan

For scanning of stone models and radiographic guides, a positioning plate is available for the system.

1. Scan the patient with an open bite by securing the bite with cotton pads.
2. Install positioning plate. Position stone model.

Note! *It is recommended to use a sponge or a foam under radiographic guide during the scan.*

3. Take scout image with default values. Correct position if needed.



4. Select same resolution and parameters as in patient scan.

Note! More detailed instructions in the CRANEX® 3D Quick Guide Stone model and radiographic guide scan protocol.

5.6 Warnings and error messages

The unit responds to error situations by showing a dialog box containing an error code and descriptive text on the touch screen.

When an error code appears on the display the unit will stop working and cannot be operated while the error code is on the display. In less severe cases a warning message will be displayed, leaving the unit operable.

5.6.1 Acknowledging errors

Most errors may be acknowledged by closing the dialog box the error is reported in. Some errors require the unit to be rebooted. If such an error occurs, or if the unit fails to operate as described in the user's manual, switch the unit off, wait a few seconds and switch the unit on again.

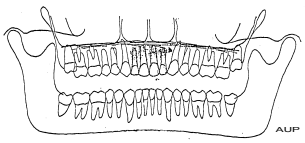
5.6.2 Image transfer errors

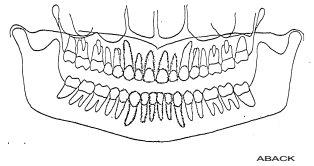
If an image is not transferred successfully to the PC, close and then reopen the dental imaging software and/or restart the PC. DO NOT restart the unit as this will erase any image that is stored in the unit memory and this retrievable image will be lost. If restarting the PC and/or restarting the dental imaging software does not allow you to retrieve the images, contact technical support without restarting the unit.

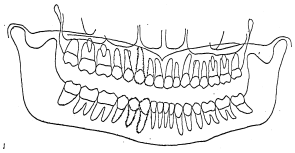
6 Troubleshooting

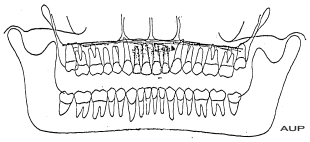
High quality images with sharp contrast and good detail provide optimum diagnostic information. Images with less quality are usually the result of one or more common problems.

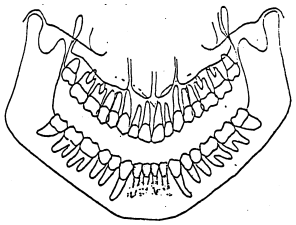
6.1 Patient positioning

Problem	Possible cause	Remedy
Incisors and canines narrow and unsharp. Overshadow in molar and premolar areas. Rows of teeth are compressed. 	1. Focal trough light set too far posterior 2. Image layer laser light not obeyed 3. Bite block was not used	1. Check patient positioning with laser light lines and occlusion correction buttons 2. Check patient positioning with laser light lines and occlusion correction buttons 3. Insert bite block

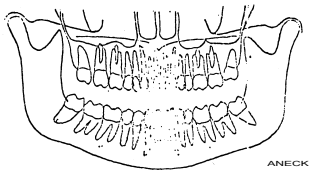
Problem	Possible cause	Remedy
Incisors and canines wide and unsharp. Rows of teeth widened. 	1. Focal trough light set too far anterior 2. Image layer laser light not obeyed 3. Bite block was not used	1. Check patient positioning with laser light lines and occlusion correction buttons 2. Check patient positioning with laser light lines and occlusion correction buttons 3. Insert bite block

Problem	Possible cause	Remedy
Teeth appear wider on one side and narrower on the opposite. Ramus widths are different on opposite sides. 	1. Midsagittal line not obeyed 2. Patient's head not in center position	1. Check patient's mid sagittal plane with laser light line 2. Check that patient's head is centered, and that the head support side clamps where closed to keep the head straight.

Problem	Possible cause	Remedy
The shadow of hard palate is exposed over maxillary molars. Row of teeth has a wavy appearance. TM joints are exposed outward. Image is not "smiling". Mandible is imaged sharper than maxilla. 	Patient head tilted back	Check FH plane

Problem	Possible cause	Remedy
Rows of teeth curved upwards. Mandibular incisors are unsharp. TMJ joints exposed high and are often cut off from the image. Image is "smiling" too much. 	Patient head tilted forward	Check FH plane

Problem	Possible cause	Remedy
Middle area of the image too bright and unsharp. Spine shadow.	Patient's neck was not stretched	Stretch patient's neck



Problem	Possible cause	Remedy
Black shadow over maxillary teeth apex area.	Tongue was not against the roof of palate.	Ask patient to swallow and place tongue against the roof of palate during the exposure.

Problem	Possible cause	Remedy
TMJ's exposed on different heights on image. Bilateral distortion in molar and premolar regions.	1. Patient tilted to one side 2. Midsagittal laser light line not obeyed.	1. Check midsagittal plane and center patient's head. 2. Check midsagittal plane and center patient's head.

Problem	Possible cause	Remedy
Rows of teeth exposed too high. TMJ's cut off.	1. Chin was not resting on chin support 2. Patient positioned too high	1. Check patient positioning and type of bite fork rod. 2. Check patient positioning and type of bite fork rod.

Problem	Possible cause	Remedy
Rows of teeth exposed too low. Mandible not exposed completely to the image.	Chin rest was not used with bite fork.	Install chin rest.

6.2 Image appearance

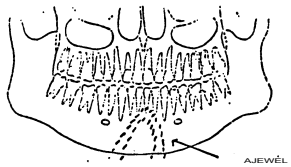
Problem	Possible cause	Remedy
Images are too light	1. SCANORA®: Contrast and brightness not optimum 2. SCANORA®: Gamma not set correctly	1. Adjust contrast and brightness. 2. Select a more fitting histogram type and check gamma setting.

Problem	Possible cause	Remedy
Images are too dark	1. SCANORA®: Contrast and brightness not optimum. 2. Manual technique factors used too high.	1. Adjust contrast and density. 2. Decrease technique factors.

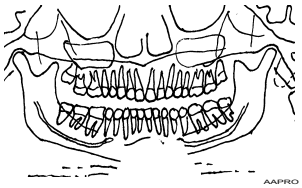
Problem	Possible cause	Remedy
Lack of image contrast	1. SCANORA®: Contrast and brightness not optimum. 2. kV used is too high. 3. Gamma value is not correct for the monitor being used.	1. Adjust contrast and brightness. 2. Lower the kV setting. 3. Adjust Gamma value

6.3 Artefacts

Problem	Possible cause	Remedy
Irregular, bright shadows or artefacts	Patient is wearing metal objects, such as earrings, necklace etc.	Ask patient to remove objects.



Problem	Possible cause	Remedy
An unexposed area is shown down in the lower middle section of the image.	Lead apron misplaced.	Check the lead apron positioning.



Problem	Possible cause	Remedy
Partial lack of detail and motion artefacts. Irregular vertical bright lines on image.	Patient has moved during the exposure.	Retake the image.

Problem	Possible cause	Remedy
Vertical dark lines on image.	Patient's shoulder in touch with machine parts.	Check patient positioning.

Problem	Possible cause	Remedy
Patient's right side tooth are not exposured.	Exposure button released prematurely.	Retake the image.

Problem	Possible cause	Remedy
Right and left image sides are uncomplete. TMJ's are not shown.	TMJ areas in sectional images where deselected.	Select all sections in panoramic image.

Problem	Possible cause	Remedy
A light horizontal line on QA image.	Bite block was left on place.	Remove the bite block and retake QA image.

Problem	Possible cause	Remedy
Horizontal lines on image.	Sensor problem.	Consult the dealer.

Problem	Possible cause	Remedy
CEPH: Lateral view has 2 ear holder pins.	1. Cephalostat lock not locked 2. Ear holders misaligned	1. Lock it 2. Call service

6.4 Unit operation

Problem	Possible cause	Remedy
Back of the patient's head is touching the x-ray tube during the exposure.	1. Patient's head inclination not correct 2. Patient is too big for the unit. 3. Patient has slumped.	If the image is not acceptable then 1. Check the head position and retake the image. 2. Check the patient positioning. Make the exposure even though the head may touch the tube head. 3. Check the patient positioning. Make the exposure even though the head may touch the tube head.

Problem	Possible cause	Remedy
Patient's shoulders are touching the x-ray tube or sensor.	Patient is too big for the unit. Wide and high shoulders.	Reverse patient's hands on handles: left to right side handle and vice versa.

7 Maintenance

7.1 Maintenance procedure

The maintenance procedure described below shall be seen as a minimum requirement and can be made more stringent to comply with regulations regarding the use and maintenance of dental x-ray devices that are in force in the country in which the unit is installed.

7.1.1 Annual maintenance

An annual maintenance procedure must be carried out at least once a year by qualified service personnel. Contact your local distributor for details.

7.1.2 Calibration intervals

To keep the image quality at best possible level, calibrations and quality checks shall be carried out at regular intervals according to the table below.

Modality	Minimum requirement	Recommendation
3D	Two (2) times annually	Four (4) times annually
Panoramic	Annually during normal maintenance	Two (2) times annually
Cephalometric	Annually during normal maintenance	Two (2) times annually

Note! *The calibrations mentioned in this manual can be done by the user or qualified service personnel.*

7.2 Changing the fuses

Main fuses are located next to the on/off power switch. Push inward on the fuse base and twist it counterclockwise with a screwdriver. The fuse with the base comes out.

Remove the fuse from the base and replace it with the new one. Repeat this with each blown fuse. Fasten both fuses by pushing the base in and twisting it clockwise with a screwdriver.

Use only appropriate fuses:

- Line voltage 220-240 Vac: 326 Littelfuse 10A (slow blow) or Cooper Bussman MDA-10 (time delay)
- Line voltage 100-120 Vac: 326 Littelfuse 15A (slow blow) or Cooper Bussman MDA-15 (time delay)

7.3 Cleaning and decontaminating the unit

CAUTION!

Switch the unit off or disconnect it from mains before cleaning the unit. If you use a spray cleaner do not spray into any ventilation grills. Do not allow water or other cleaning liquids to enter the unit interior since these may cause short-circuits or corrosion. The unit should be cleaned after every usage.

CAUTION!

Clean the dust off the unit regularly. The unit might overheat if excess dust is gathered on the cooling grilles.

Unit surfaces

All surfaces can be wiped clean with a soft cloth dampened with a mild detergent, e.g. soapy water. DO NOT use abrasive cleaning agents or polishes on this equipment.

Positioning light covers

The positioning light covers are made of clear plastic. Use a soft cloth dampened with a mild detergent, e.g. soapy water. NEVER use abrasive cleaning agents or polishes to clean the covers.

Surfaces that the patient touches

All surfaces and parts that the patient touches or comes into contact with must be decontaminated after each patient. Use a disinfectant that is formulated specifically for decontaminating dental equipment and use the disinfectant in accordance with the instructions supplied with the disinfectant. All items and surfaces should be dried before next usage.

Note! *Wear gloves and other protective equipment during decontamination process. In accordance with the instructions supplied with the cleaner.*

WARNING!

Do not use any disinfecting sprays since the vapor could ignite causing injury.

Decontamination techniques for both the unit and the room must comply with all laws and regulations within the local jurisdiction.

Examples of cleaning agents that can be found in disinfectant products which are allowed or prohibited **when cleaning the unit**:

Allowed: Methanol (metyl alcohol), Soap, Isopropyl alcohol, distilled water.

Not allowed: Bentzene, Chlorine bentzene, Acetone, Acetic ether, agents containing phenol, paracetic acid, peroxide and other oxygen-cleaving agents, sodium hypochlorite and iodine-cleaving agents.

Autoclave

Some removable parts in contact with the patient may be autoclaved. These parts are: bite rods, bite guides and chin supports.

If autoclaving is performed for these items, disinfection by alternate methods is not needed.

Steam sterilization

Recommended parameters for sterilizable parts are:

- Gravity-displacement steam sterilization
  "Flash" sterilization:
  Temperature: 270 F (132°C)
  Exposure time: 3 minutes
- Prevacuum steam sterilization
  "Flash" sterilization:
  Temperature: 270 F (132°C)
  Exposure time: 3 minutes
- Steam-flush pressure-pulse steam sterilization
  Temperature: 270 F to 275 F (132°C to 135°C)
  Exposure time: 3 to 4 minutes

8 Calibration and adjustment

8.1 Introduction

Calibrations and quality checks are performed by taking exposures of calibration tools. The system does needed adjustments according to the image data captured. For panoramic and cephalometric quality checks the quality is visually evaluated by the operator.

Resulting from the each calibration is an image containing calibration results, telling the operator how to proceed with the calibration and adjustment procedure. In addition to the calibration name (e.g. Adjustment panCol) the images contain image data sampled during the calibration, adjustment instructions and a "Passed / Not Passed / Failed" calibration status.

- **Passed** means that the calibration program is successfully done. Move on to next calibration.
- **Not passed** means that adjustment is still needed. Follow the instructions the image (if any) and take another exposure. Some calibration programs are iterative and demand a few repetitions.
- **Failed** means that the system could not decide what adjustment should be done in order for the calibration to succeed. This calibration status is always the result of some error condition. Taking another exposure will not help. The image may give a hint on what the problem is (e.g. no radiation, collimator severely tilted, image data corrupted…). Contact service if the problem persists after restarting the unit and PC.

8.2 Preparing for calibration

1. Close the head support and lock it in its upmost position.

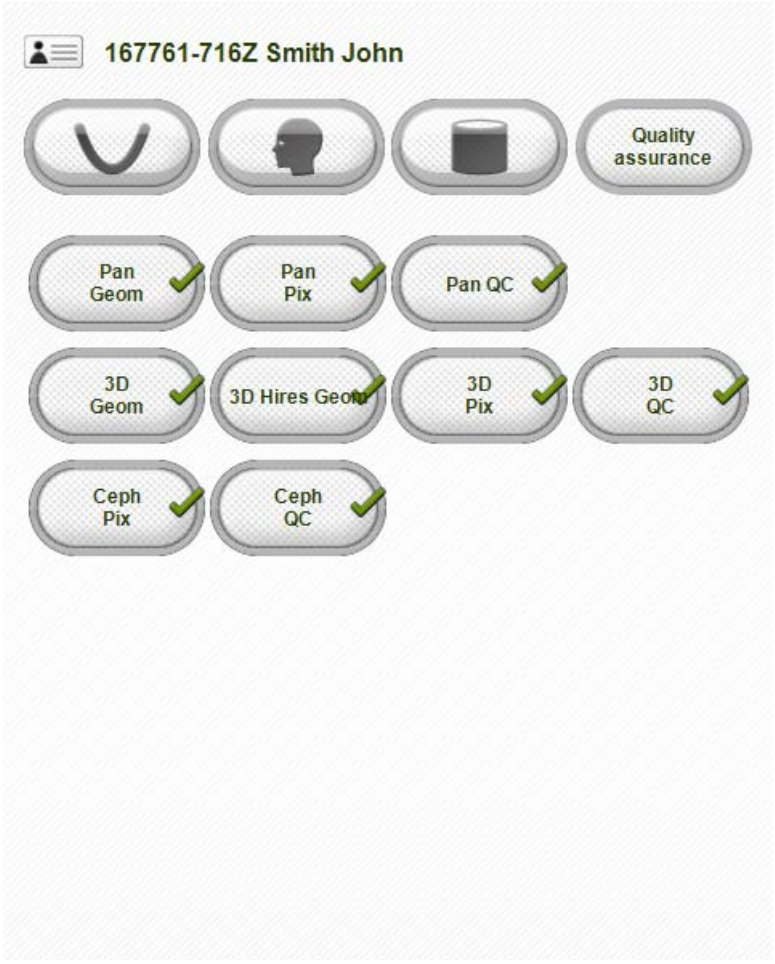
2. Switch the PC and unit on.

3. **PC:** Open the dental imaging software and then open a patient (card) and give it and identifiable name, for example: calibration (refer to the user's manual supplied with the dental imaging software for more information).

4. **PC:** Click the image acquisition button to activate image capture.

5. Touch the **settings** button on the touch screen display.

6. Select the **Quality assurance** button.
   The calibration display appears.



8.3 Panoramic calibration

8.3.1 Panoramic geometry calibration

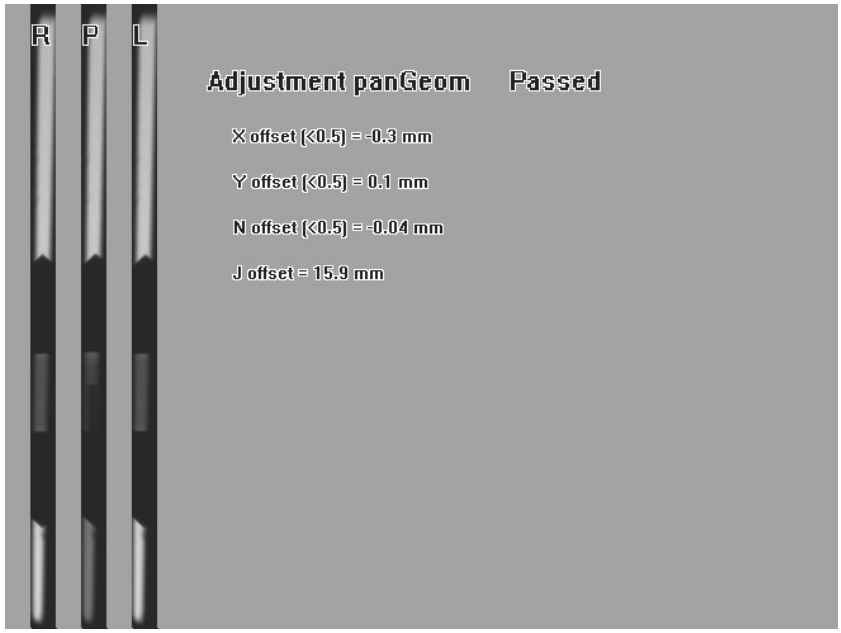
1. Select the program.

2. Press **Return**.

3. Install the double cone calibration tool.

4. Take an exposure.

5. Repeat the calibration until calibration result “passed” is achieved.



8.3.2 Panoramic pixel calibration

Note! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

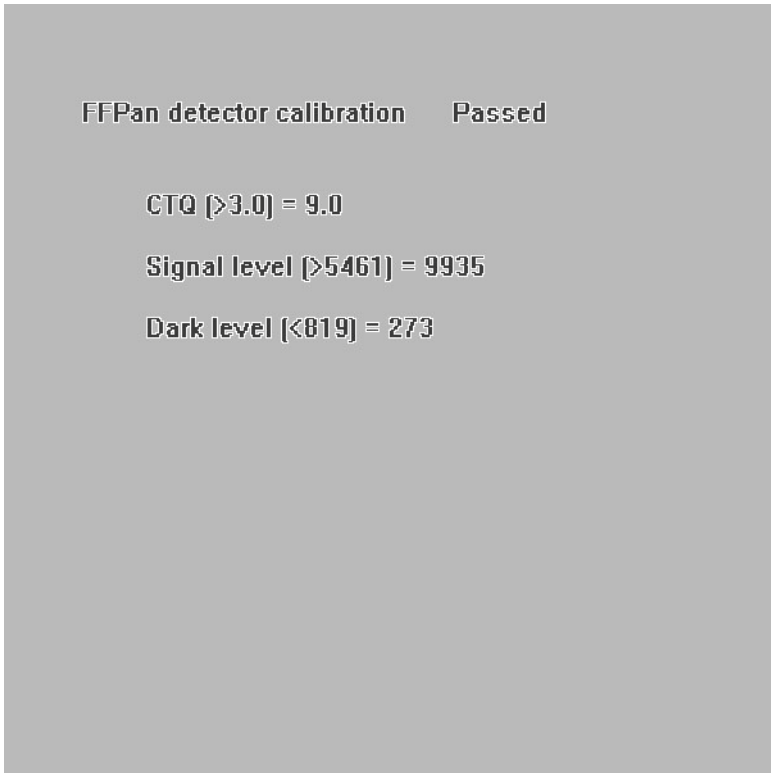
Note! *Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.*

1. Remove the calibration tools.

2. Select the program.

3. Press **Return**.

4. Take an exposure.



8.3.3 Panoramic Quality Check (optional)

Note! *Use the same tool for cephalostat Quality Check.*

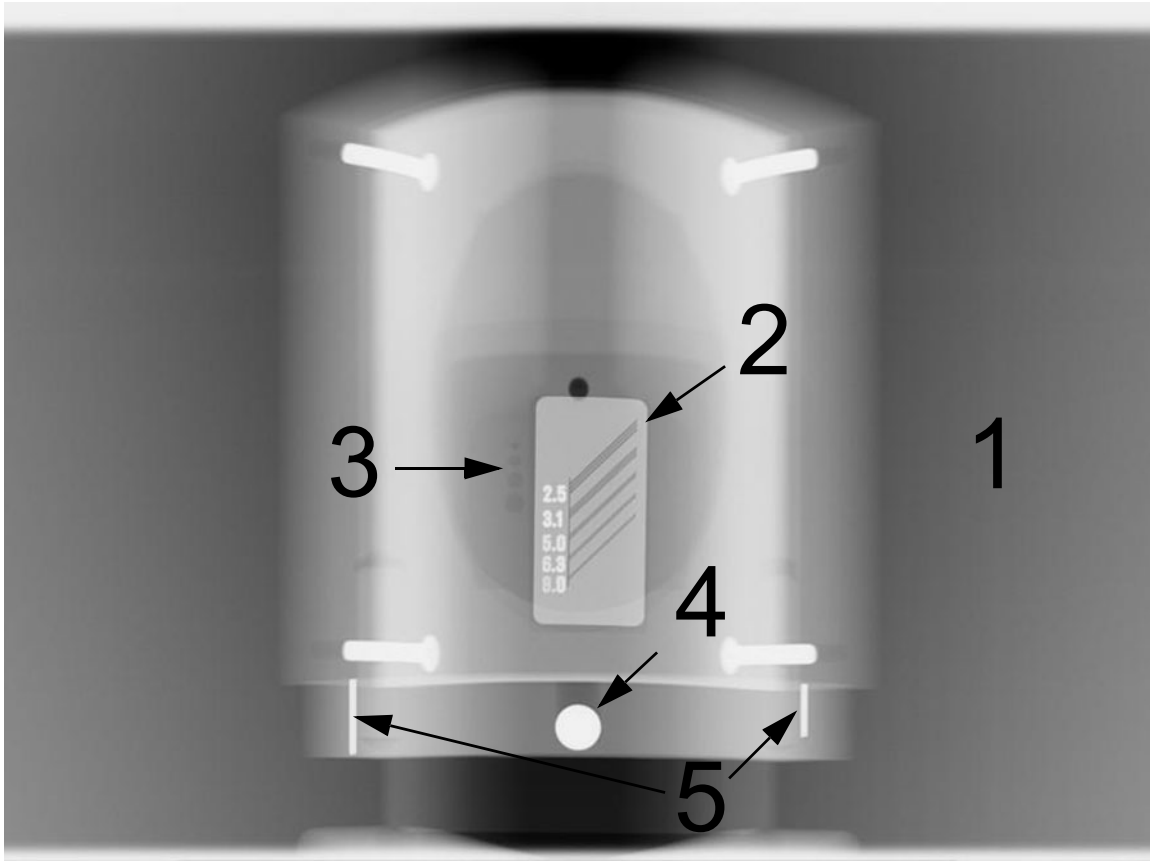
1. Attach a panoramic Quality Check Tool (optional) to the chin support.

2. Select the Pan QC program.

3. Press **Return**.

4. Take an exposure.

5. Visually evaluate the result using the installed imaging software.



Subjects to be evaluated:

1. Smoothness of the exposed area. Non-exposed area surrounds the whole image.

2. High contrast resolution; minimum 3.1LP/mm must be distinguishable.

3. All four low contrast holes must be visible.

4. Roundness of the ball.

5. The ball should be placed symmetrically between the two pins. The distance from both pins to center should be equal length.

Note! *The panoramic QC collimator is equipped with a 0.8 mm copper filter. If more filtration is required, additional filtration may be attached to the tubehead cover. The unit may be configured to use higher exposure values to compensate for an additional 1 mm copper filter.*

Ask Technical Support to adjust the copperthickness setting as required.

8.4 3D calibration

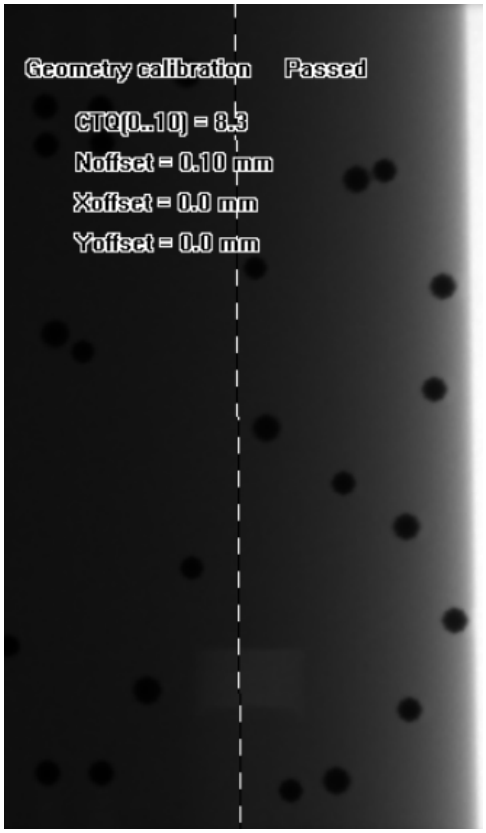
8.4.1 3D geometry calibration

1. Attach the base of the phantom to the lower shelf. Level it with the bubble.

2. Select the program.There is a calibration procedure for both 3D imaging modes, standard and high resolution. Standard geometry calibration has to be done first.

3. Press **Return**.

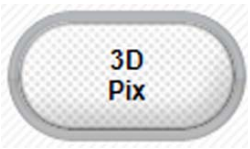
4. Install the 3D calibration phantom.



5. Take an exposure.

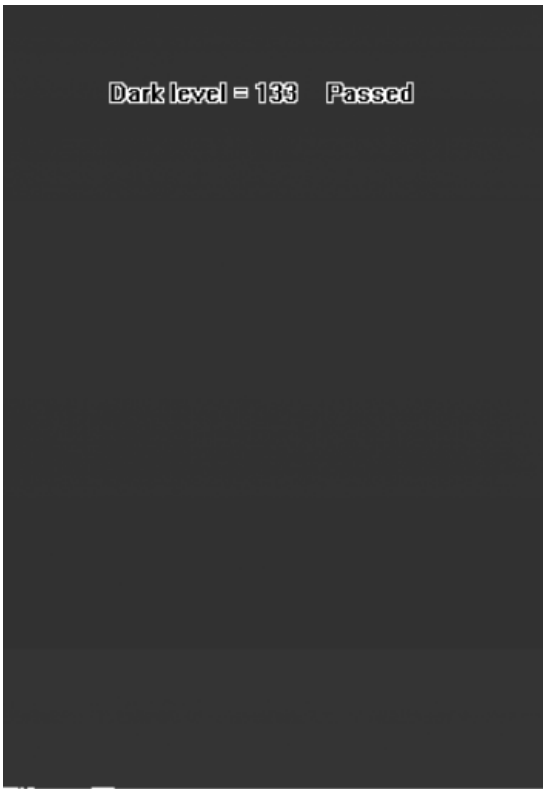
6. Repeat the calibration until calibration result “passed” is achieved. This calibration is only needed with 3D units.

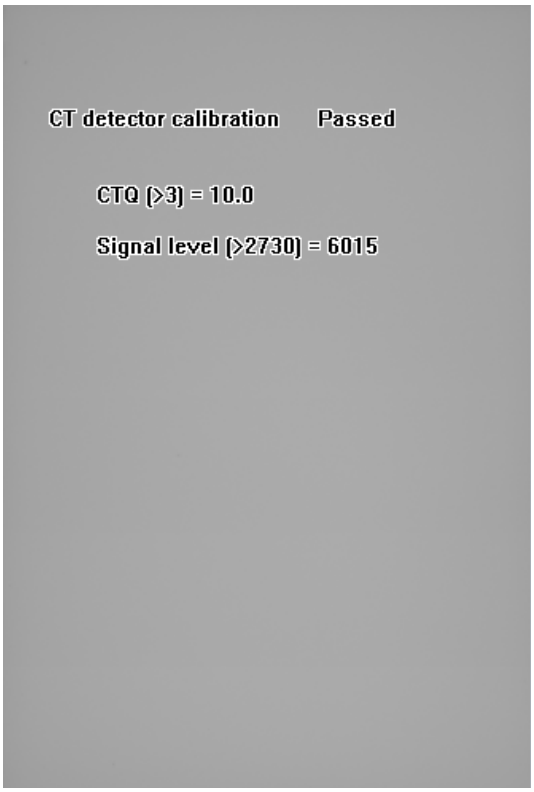
8.4.2 3D pixel calibration



1. Remove the 3D calibration phantom.
2. Select the program.

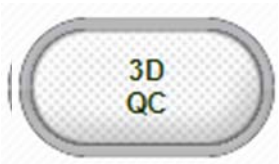
3. Press **Return**.
4. Take an exposure. The result image informs when the calibration is passed.





8.4.3 3D Quality Check program

1. Attach the QC phantom to the unit.

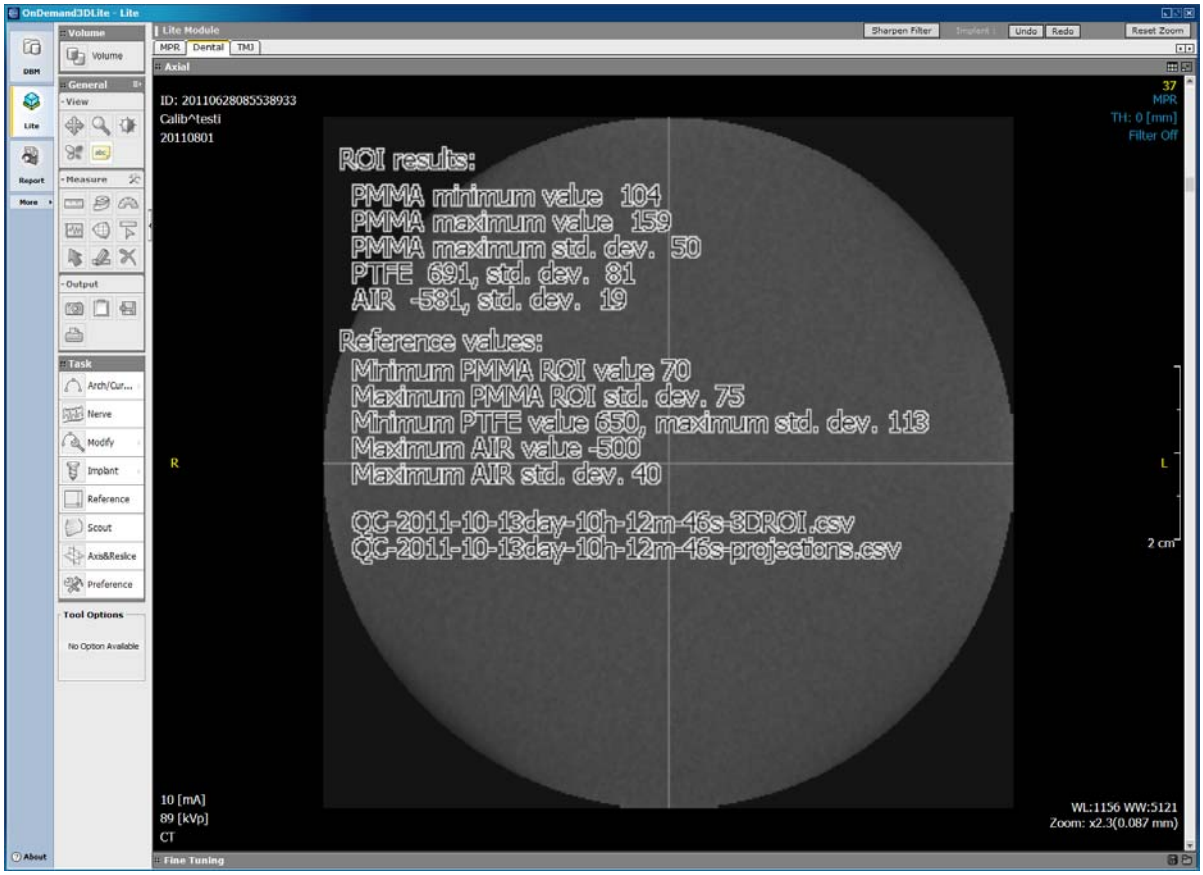


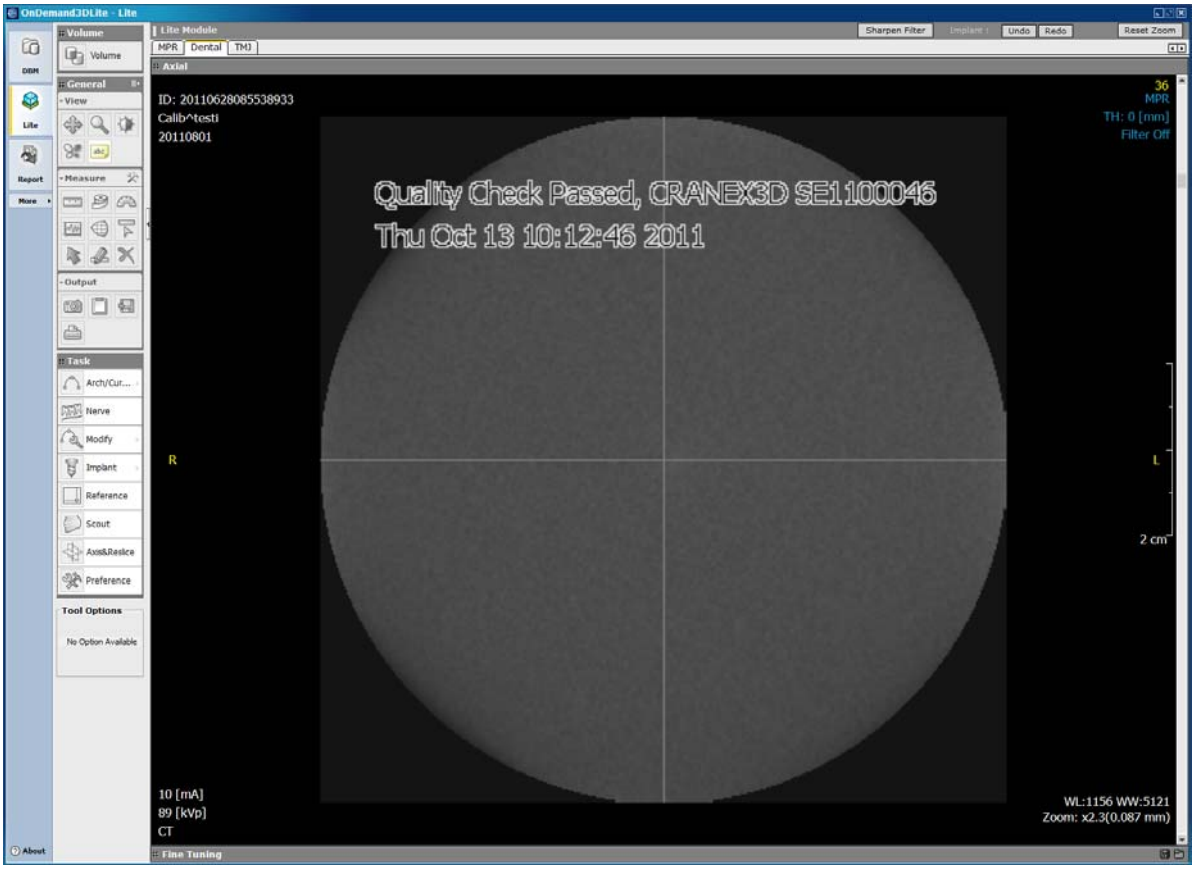
2. Select the 3D QC program.

3. Press **Return**.

4. Take an exposure.

5. Review, with 3D viewing software from the axial view by scrolling the slices the info about calibration result. The resulting image contains information on whether the quality check was passed. Repeat until quality check is passed.


ID: 20110628085538933
Calib^testi
20110801
ROI results:
PMMA minimum value 104
PMMA maximum value 159
PMMA maximum std. dev. 50
PTFE 691, std. dev. 81
AIR -581, std. dev. 19
Reference values:
Minimum PMMA ROI value 70
Maximum PMMA ROI std. dev. 75
Minimum PTFE value 650, maximum std. dev. 113
Maximum AIR value -500
Maximum AIR std. dev. 40
QC-2011-10-13day-10h-12m-46s-3DROI.csv
QC-2011-10-13day-10h-12m-46s-projections.csv
10 [mA]
89 [kVp]
CT
WL:1156 WW:5121
Zoom: x2.3(0.087 mm)


ID: 20110628085538933
Calib^testi
20110801
Quality Check Passed, CRANEX3D SE1100045
Thu Oct 13 10:12:46 2011
10 [mA]
89 [kVp]
CT
WL:1156 WW:5121
Zoom: x2.3(0.087 mm)

8.5 Cephalometric calibration

8.5.1 Ceph pixel calibration

Note! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

Note! *Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.*

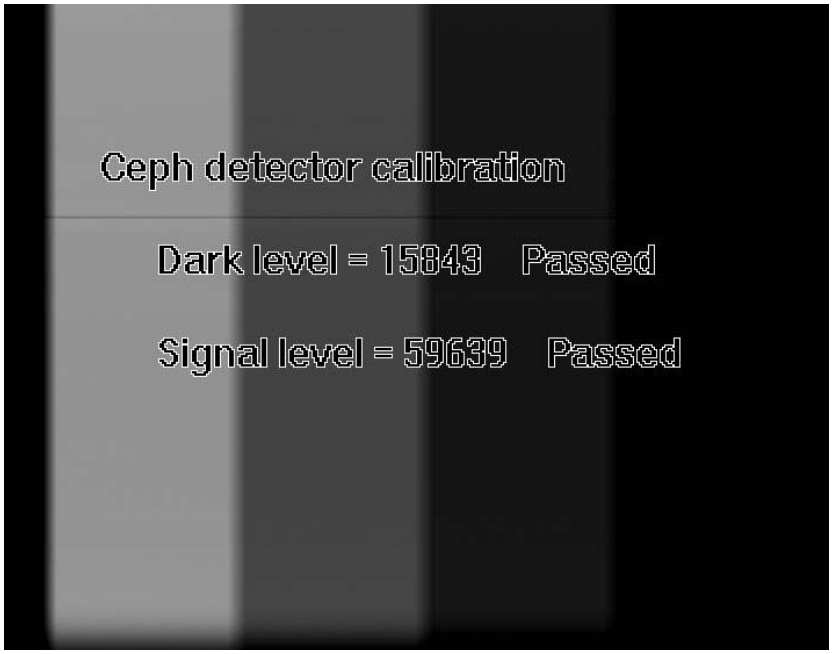
1. Rotate the ear holders into PA view position and move them completely apart. Turn nasion support up out of the way.

2. Select Ceph Pix program.

3. Press **Return**.

4. Take an exposure.

5. This calibration should always be a pass.



8.5.2 Ceph Quality check program (Optional)

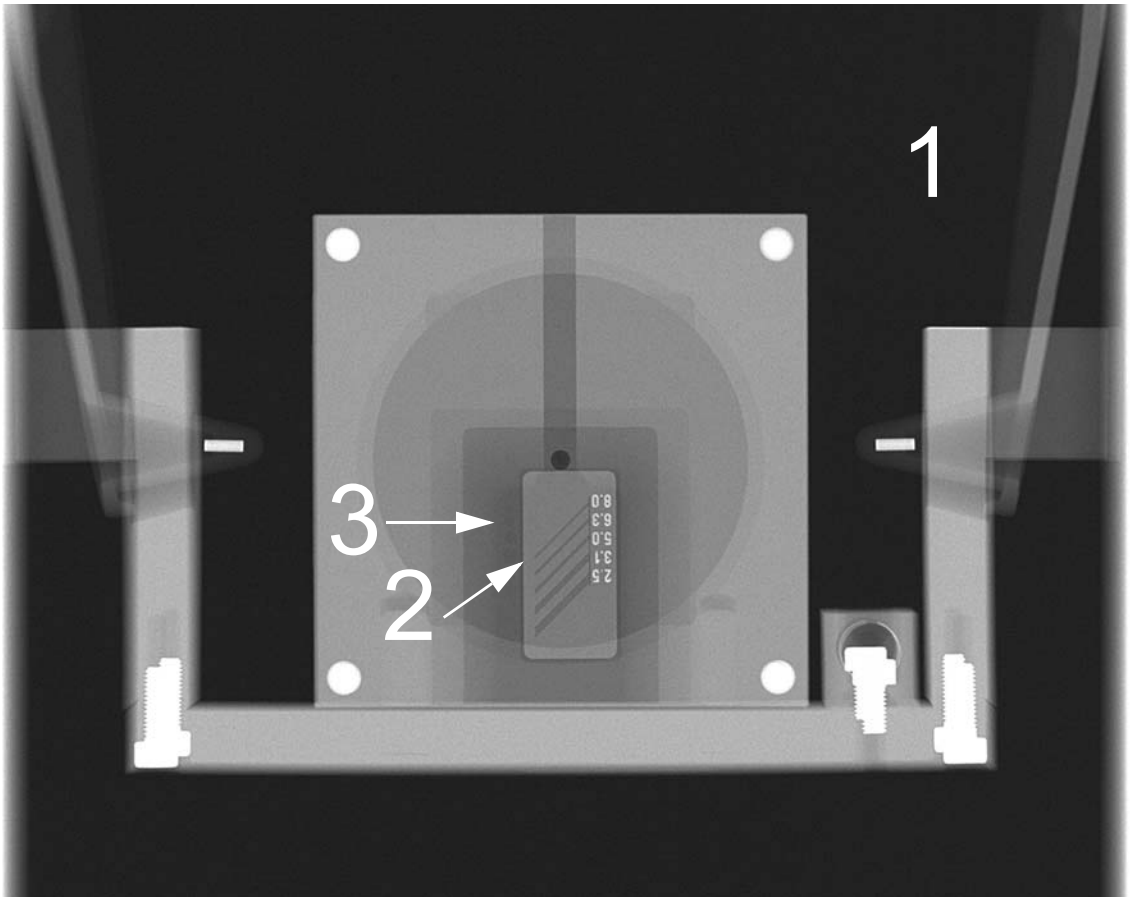
1. Attach the QC phantom to the ceph unit and ensure that it's leveled from the spirit level.

2. Select the Ceph QC program.

3. Press **Return**.

4. Take an exposure.

5. *Visually evaluate the result using the installed imaging software.*



Subjects to be evaluated:

1. Smoothness of the exposed area. Non-exposed area surrounds the whole image.

2. High contrast resolution; minimum 3.1LP/mm must be distinguishable.

3. All four low contrast holes must be visible.

9 Technical data

9.1 Technical specifications

Manufacturer	SOREDEX, PaloDEx Group Oy Nahkelantie 160 (P.O. Box 148) FIN-04300 Tuusula, FINLAND
Quality system	In accordance with ISO13485 and ISO9001 standard
Environmental management system	In accordance with ISO14001 standard
Conformity to standards:	IEC 60601-1: 1988 and A1+A2 IEC 60601-1-1: 2000 IEC 60601-1-4: 1996 and A1 IEC 60601-2-7: 1998 IEC 60601-2-28: 1993 IEC 60601-2-32: 1994 IEC 60601-1-2: 2001 and A1 IEC 60601-1-3: 1994 UL 60601-1: 2003 CAN/CSA –C22.2 No. 601-1-M90 and S1+A2 standards This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture. CRANEX® 3D is in conformity with the provisions of Council Directive 93/42/EEC as amended by the Directive 2007/47/EC concerning medical devices. Performance Standards and European Union Directive 93/42/EEC (Medical Devices Directive).

Product name	**CRANEX® 3D**
Model:	PP3-1 CRANEX® 3D
Product type:	Digital dental imaging system with panoramic, cephalometric and Cone Beam 3D imaging programs.

Unit data	
Protection against electric shock	Class I
Degree of protection	Type B applied with no conductive connection to the patient
Protection against the ingress of liquids	IP20
Disinfection methods	- mild soapy water (non-abrasive) - non-alcohol based disinfectant for the chin rest - disposable plastic covers for bite block, chin rest and chin support
For use	In environments where no flammable anaesthics nor flammable cleaning agents are present
Mode of operation	continuous operation/intermittent loading
Safety	IEC 60601-1
EMC Classification	Class B

Tube head assembly	
Tube head assembly type	THA 300
Tube type	Toshiba D-052SB, D-054SB-C Stationary anode
Tube voltage	57 - 90 kV
Max. tube current	16 mA
Max. electric output	1,44 kW
Target angle	5 degrees
Focal spot	0,5 x 0,5 mm (IEC 336/1982)
Nominal anode input	1750 W
Reference axis	In the middle of the panoramic sensor´s active area
Max. anode heat content	35 kJ
Max. X-ray tube assembly heat content	385 kJ
Max. continuous heat dissipation of the X-ray tube assembly	38 W
Total filtration	>3,2 mm Al
Leakage Technique Factors	90 kV /4 mA

Electrical connections	
Nominal mains voltage	100 - 240 Vac (Selectable)
Input power frequency	50 / 60 Hz
Nominal current	10A @ 230 VAC, 15A @ 110 VAC
Fuses	230 Vac: Littelfuse 326 (slow blow) 10A Cooper Bussman (time delay) MDA-10 110 Vac: Littelfuse 326 (slow blow) 15A Cooper Bussman (time delay) MDA-15
Power consumption	2.3 kVA @ 230 VAC, 1.65 kVA @ 110 VAC
Maximum impedance of main	0,2 Ω

Positioning laser lights	
Panoramic, TMJ & Maxillary Sinus Programs Cephalostat FH laser light 3D imaging programs	laser light (CLASS 1 LASER PRODUCT) max output 100µW Warning symbols are placed next to the laser lights and the label describing the laser light classification is placed inside the carriage side cabinet. USA / Canada models have different types of laser light stickers according to local requirements. Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
	IEC 60825-1:1993+A1:1997+A2:2001

High frequency DC generator	
Nominal power	1750 W nominal at 90 kV, 12 mA
Anode voltage	57 - 90 kV (+/- 5 kV)
Anode current	3,2 - 16 mA (+/- 1 mA)
Focal spot	0.5 mm
Minimum total filtration	3.2 mm Al
Supply frequency	75 - 150 kHz
Spine compensation	kV / mA compensated

User interface	
Program and technique factors selection, exposure control	Touch screen panel, optional remote exposure switch
Patient positioning	Positioning panel, integrated
Connection cable (CRANEX® 3D - PC)	CAT6 Ethernet cable

Panoramic programs & Technical factors & magnification:		
Standard Adult Panoramic	57-90 kV/ 3.2-16 mA/16.4 s	30%
Child Panoramic	57-90 kV/ 3.2-16 mA/14.4 s	30%
TMJ PA	57-90 kV/ 3.2-16 mA/10.6 s	23%
TMJ Lateral	57-90 kV/ 3.2-16 mA/11.2 s	55%
Maxillary Sinus	57-90 kV/ 3.2-16 mA/12.5 s	30%
Bitewing (BW)	57-90 kV/ 3.2-16 mA/11.9 s	30%
Panoramic QC	57-90 kV/ 3.2-12.6 mA/16.4 s	30%

Exposure Control	Automatic Exposure Setting (AES) based on patient head size	

Cephalometric programs & Technical factors:	
Reduced width lateral view	85-90 kV / 8-12.6 mA / 6.9-14 s
Full width lateral	85-90 kV / 8-12.6 mA / 10-20 s
PA/AP, facial and oblique views	80-90 kV / 8-12.6 mA / 10-20 s
Carpus program (optional) (Not in USA and Canada)	60-90 kV / 3.2-12.6 mA / 8-20 s
Exposure Control	Automatic Exposure Setting (AES) based on patient head size
Magnification factor	1.15 (15%)

3D imaging programs:	
XS FOV dimensions	61 x 41 mm (HxD)
Midi FOV (optional) dimensions	61 x 78 mm (HxD)

3D imaging programs:	
XS FOV standard resolution	90 kV / 6.3 - 12.5 mA / 2.3 s
Midi FOV (optional) standard resolution	90 kV / 6.3 - 12.5 mA / 4.9 s
XS FOV High resolution and Endo program	90 kV / 4 - 12.5 mA / 6.1 s
Midi FOV (optional) High resolution	90 kV / 4 - 10 mA / 12.6 s
XS FOV scout	90 kV / 4 - 12.5 mA / 0.02 s
Midi FOV (optional) scout	90 kV / 4 - 12.5 mA / 0.04 s

Image storing and retrieving:	
File formats	PNG (16-bit), JPG (12-bit)
File compression	PNG (lossless), JPG (100%-60% quality)
Typical panoramic file size	About 2-4 MB (PNG 16 bits)
Typical cephalometric file size	3-5 MB (PNG 16 bits)
Typical 3D file size	150-250 MB (DICOM)
Patient database	Standalone workstation Server on local area network (LAN)

Panoramic patient positioning	
Operation	Left Motorised carriage movement
Positioning aids	Chin rest, bite block, 3-point headrest Hinged mirror, 3 positioning laser lights, Y-layer step less adjustment

Cephalostat patient positioning	
Operation	Arm mounts on left or right side of the unit Interlocked pan/ceph sensor Motorised carriage buttons at cephalostat head assembly.
Positioning aids	Ear holders, Nasion support with vertical mm scale, Frankfort horizontal plane laser light, Contact plate (Carpus program).

3D imaging patient positioning	
Operation	Left or right side of unit Motorised carriage movement
Positioning aids	Chin rest, chin support, chin cup 3-point headrest, hinged mirror, 3 positioning laser lights

Cephalostat scanning	
Scanning method	Horizontal scan, synchronized sensor and secondary slot motion
Scanning time	10 - 20 s.

Panoramic image receptor	
Sensor unit	Pan sensor or interchangeable Ceph sensor
Technology	CMOS
Image pixel size and depth	100 x 100 μm and 14 bits
Active area height	5.8 inches / 148 mm / 1480 pixels
Resolution	Pan: 5 LP/mm

Cephalometric image receptor	
Sensor unit	interchangeable Ceph sensor
Technology	CMOS
Image pixel size and depth	100 x 100 μm and 14 bits
Active area height	223,2 mm / 2232 pixels
Image field width in lateral view	10.2 inches / 260 mm, maximum 6.7 inches / 170 mm, minimum
Image field width in PA view	7.9 inches / 200 mm
Resolution	4 LP/mm (cephalometric)

3D image receptor	
Sensor unit	3D sensor
Technology	CMOS Flat panel
Image pixel size and depth	200 μm and 13 bits
Active sensor surface (H x W)	100 x 68 mm

Unit physical measures:	
source-image distance (SID)	500 mm (Panoramic) 570 mm (3D)
Installation	Standard wall mount with ±45° angled joint. Optional base for free standing unit (unit height is increased 25 mm).
Height x Width x Depth (inches/mm)	2414x965x1126mm (standard column) 94.9 x 38 x 44.3 inches -Max.
Weight	200 kg / 440 lbs. (Panoramic)

CRANEX® 3D ceph physical measures:	
source-image distance (SID)	68.7 inches / 1745 mm
source-object distance (SOD)	60 inches / 1520 mm
Installation	Standard wall mount with 45° angled joint. Optional base for free standing unit (unit height is increased 25 mm)
Height x Width x Depth (inches/mm)	2414 x 1872 x 1126 mm 94.9 x 73.7 x 44.3 inches
Weight	250 kg / 551 lbs. (Cephalometric)

Ambient temperatures:	
Transportation and Storage	-10°…+60°C
Operation Temperature	+10°...+35°C, RH max. 85%

Minimum PC requirements for 3D acquisition workstation	
Processor	2.5 GHz dual core, or better
Memory	3 Gigabytes RAM, or more
Hard disk	500 GB, or more
Expansion slot	PCI-Express bus for supplied GPU, full length
Power supply	500 watt minimum
Network	Gigabit Ethernet 1000Base-T
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Display	20" LCD display, 1600 x 1200 or 22" LCD widescreen display, 1680 x 1050, or better
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Graphics board	The system is highly dependent on the used graphics board and graphics driver of the reconstruction workstation. Consult technical support for information on the supported boards and drivers. Examples of supported boards: NVidia Quadro 4000 NVidia GeForce GTX 560 The compatible graphics driver versions are found on the driver update DVD.
PCI board connection	Full-length PCIe x16 slot (for GPU board)

Minimum PC requirements for 3D acquisition workstation	
USB	USB ports (for HASP Dongle keys) • 1 for reconstruction system • 1 for 3D viewing SW (if needed)
Mouse	Mouse with scroll wheel

Minimum PC requirements for 2D acquisition workstation *	
Processor	2.5 GHz dual core, or better
Memory	3 Gigabytes RAM, or more
Hard disk	500 GB, or more
Graphics board	NVidia GeForce 6600 or ATI Radeon X700 or better; 256MB or more memory (integrated graphics are not supported)
Power supply	500 watt minimum
Network	Gigabit Ethernet 1000Base-T
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Display	20" LCD display, 1600 x 1200 or 22" LCD wide screen display, 1680 x 1050, or better
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Mouse	Mouse with scroll wheel
OpenCL support	OpenCL 1.1 supported by either processor or graphics adapter

* These requirements are valid only if driver update 11.4 or later is used. For earlier versions see table Minimum PC requirements for 3D acquisition workstation.

Note! *This is an abbreviated list of requirements. Please refer to the software installation manual or contact your local dealer for detailed installation requirements.*

Minimum PC requirements for 2D/3D Viewing workstation *	
Processor	2.0 GHz dual core, or better
Memory	2 Gigabytes RAM, or more
Graphics board	NVIDIA GeForce 6600 or ATI Radeon X700 or better; 256MB or more memory (integrated graphics are not supported)
Hard disk	3 GB free space, or more
Network	Gigabit Ethernet 1000Base-T (recommended) or Fast Ethernet 100Base-TX
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Display	19" LCD display, 1280 x 1024, or better

* For the PC requirements of the 3D viewing software consult the 3D software manuals.

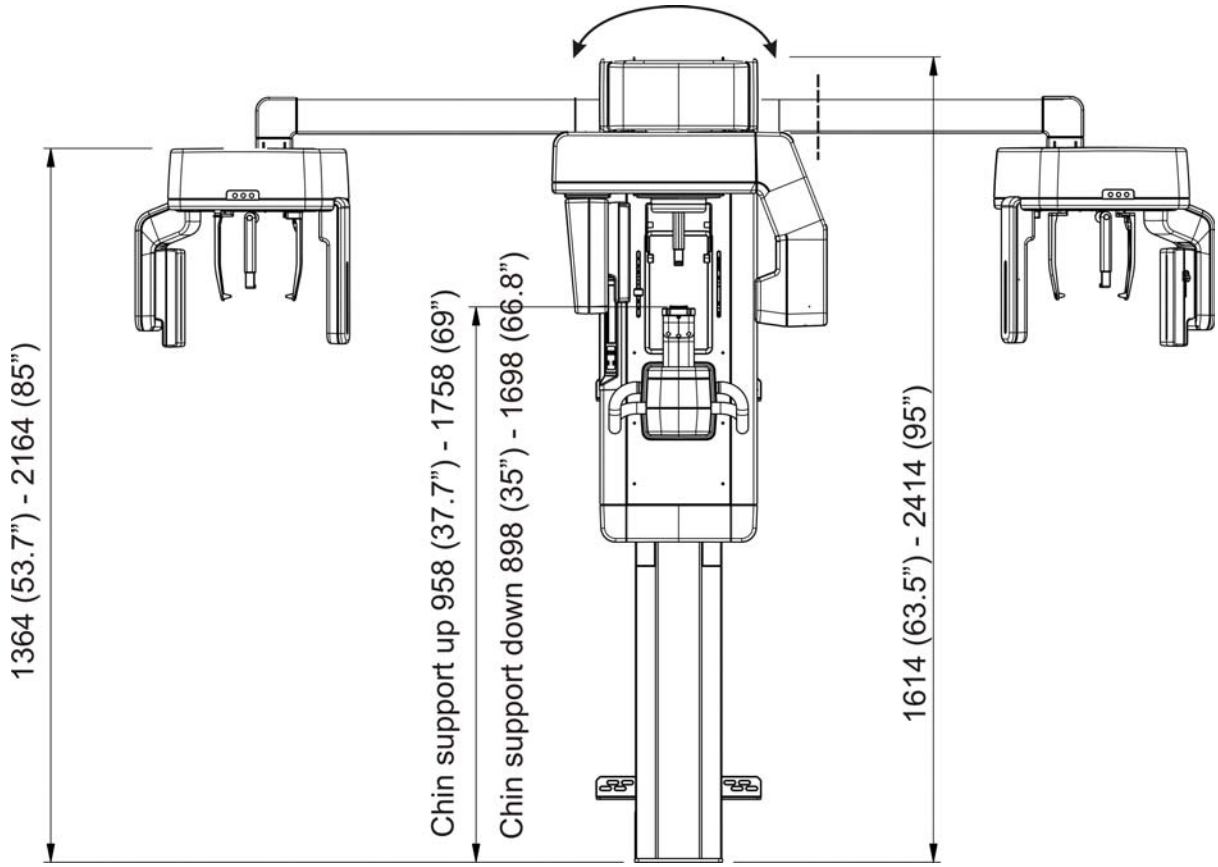
System requirements and connections

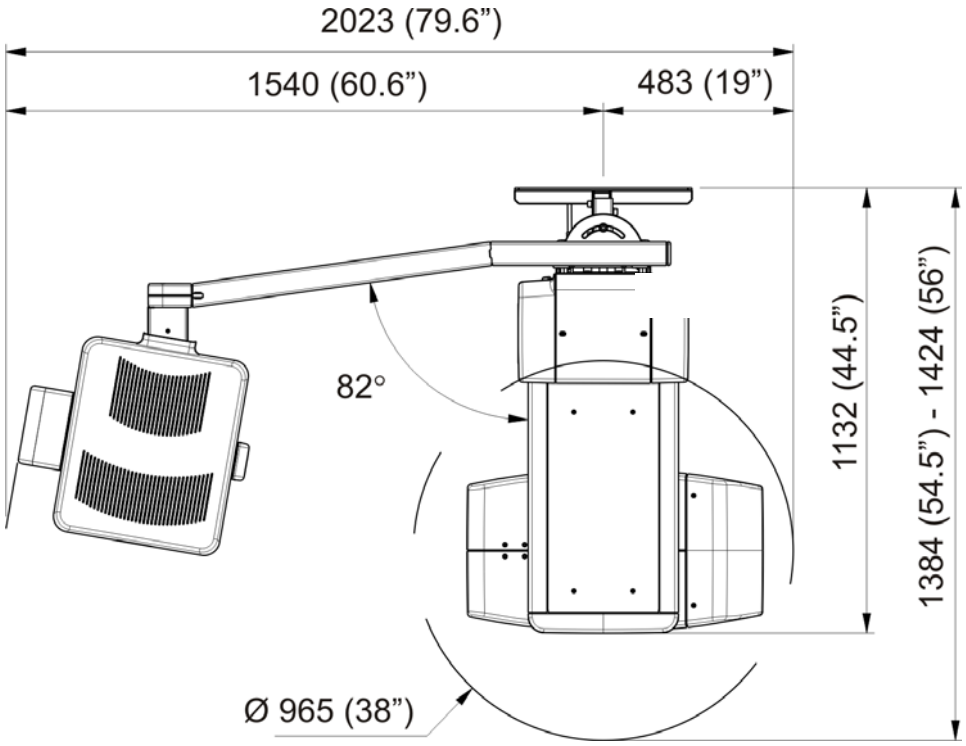
- The PC and any other external device(s) connected to the system must meet the IEC 60950 standard (minimum requirements). Devices that do not meet the IEC 60950 standard must not be connected to the system as they may pose a threat to operational safety.
- The PC and any other external devices must be connected in accordance with IEC 60601-1-1.
- The x-ray unit must be connected to it’s own separate power supply. The PC and any other external devices must NOT be connected to the same power supply as the x-ray unit.
- Position the PC and any other external device at least 1.5 m (60”) from the xray unit so that the patient cannot touch the PC or any other external device while being x-rayed.
- The PC and any other external devices shall not be connected to an extension cable.
- Multiple extension cables shall not be used.
- Do not position the PC where it could be splashed with liquids.
- Clean the PC in accordance with the manufacturer’s instructions.

Ceph ready option (Ordered separately)	
Options	**Description**
Ceph Upgrade to CRANEX® 3D pan	Upgrade CRANEX® 3D panoramic with Cephalometric imaging.

Field upgrades for model CRANEX® 3D	
Upgrade	**Description**
Cephalostat Upgrade	Add ceph imaging to CRANEX® 3D pan
3D XS or MIDI FOV Upgrades	Add 3D option to CRANEX® 3D

9.2 Unit dimensions





Note! *The cephalostat arm and the touchscreen can be on either side (L/R).*

9.3 Symbols that appear in the unit

Radiation warning

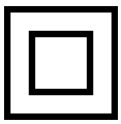
Dangerous voltage

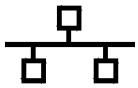
On or enabled

Off or disabled

Exposure switch

Connector for exposure switch


CLASS II equipment
(Double insulated electrical appliance)


Ethernet connector

Operating instruction
(More details in operation instructions)

Laser radiation

Attention, consult accompanying documents

Ground (Functional)

Protective ground

Laser class label (Patient positioning lights)

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Type B equipment

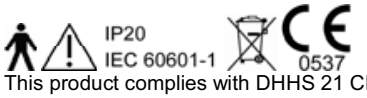
CE (0537) symbol
MDD 93/42/EEC

ETL Classified conforms to UL STD 60601-1.
Certified to CSA.

9.4 Labels on the unit

The main label of the unit is located on the vertical carriage next to the on/off power switch. The unit is class I, type B and with IP20 protection.

Type: PP3 - 1
Ser. No:
Manufactured:
10 A 220 - 240 V~ 50 / 60 Hz (1A continuous)
15 A 100 / 120 V~ 50 / 60 Hz (1A continuous)



This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture.
Rx only.

Warning:
This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

ETL CLASSIFIED
CONFORMS TO UL STD 60601-1.
CERTIFIED TO CSA
STD C22.2 NO 601.1.

Manufactured by Soredex
Nahkelantie 160
FI-04300 TUUSULA, Finland

D502470

9.5 Electromagnetic Compatibility (EMC) tables

Note! *Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.*

Table 1.1 Electromagnetic emissions IEC 60601-1-2 Ed2

CRANEX® 3D is suitable for use in the specified electromagnetic environment. The purchaser or user of CRANEX® 3D should assure that it is used in an electromagnetic environment as described below:		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Radio-Frequency Emissions CISPR11	Group 1	CRANEX® 3D uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR11	Class B	CRANEX® 3D is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	IEC 61000-3-2 Class A	CRANEX® 3D is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	CRANEX® 3D is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 1.2 Electromagnetic immunity IEC 60601-1-2 Ed2

CRANEX® 3D is suitable for use in the specified electromagnetic environment. The purchaser or user of CRANEX® 3D should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality is that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality is that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT)	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT)	Mains power quality is that of a typical commercial and/or hospital environment. If the user of CRANEX® 3D requires continued operation during power mains interruptions, it is recommended that CRANEX® 3D be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 1.3 RF immunity of non-life-support equipment or system IEC 60601-1-2

<table>
<tr><th colspan="4">CRANEX® 3D is suitable for use in the specified electromagnetic environment. The purchaser or user of CRANEX® 3D should assure that it is used in an electromagnetic environment as described below:</th></tr>
<tr><th>Immunity Test</th><th>IEC 60601-1-2 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment</th></tr>
<tr><td>Conducted RF IEC 61000-4-6

Radiated RFIEC 61000-4-3</td><td>3 V150 kHz to80 MHz

3 V/m80 MHz to2,5 GHz</td><td>[V1] 3 V

[E1] 3 V/m</td><td>Portable and mobile RF communications equipment are used no closer to any part of CRANEX® 3D, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Recommended Separation Distance:

$d = [\frac{3,5}{V_1}]\sqrt{P}$

$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz

$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:

 </td></tr>
<tr><td colspan="4">*Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe CRANEX® 3D to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating CRANEX® 3D.
**Over the frequency range 150 kHz to 80 MHz, field strengths are less than [V1] V/m.The Recommended Separation Distances are listed in the next table.Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
</table>

Note! *RF communications equipment can effect medical electrical equipment.*

Note! *This equipment generates, uses and can radiate radio frequency energy. If not installed and used in accordance with this manual, it may cause harmful interference to radio communications. Portable and mobile RF communications equipment can also affect the performance of CRANEX® 3D.*

Table 1.4 Table 4

Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
Frequency of Transmitter Equation Rated Maximum Output Power of Transmitter (watts)	150KHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ Separation Distance (meters)	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$ Separation Distance (meters)	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ Separation Distance (meters)
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,34
10	3,69	3,69	7,38
100	11,67	11,67	23,34

USE LIMITATION:

External components

The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of the EQUIPMENT and/or SYSTEM

INSTALLATIONS REQUIREMENTS & ENVIRONMENT CONTROL:

In order to minimize interference risks, the following requirements shall apply.

Cables shielding & grounding

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

Electrostatic discharges environment & recommendations

In order to reduce electrostatic discharge interference, a charge dissipative floor should be installed to prevent charge accumulation.

- The dissipative floor material must be connected to the system reference ground, if applicable.
- Relative humidity must be maintained above 30 percent.

Stacked components & equipment

The CRANEX® 3D should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the CRANEX® 3D should be observed to verify normal operation in the configuration in which it will be used.

Interference may occur in the vicinity of equipment marked with the following symbol:

No portable or mobile RF communications equipment may be used closer to any part of the CRANEX® 3D, including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.
See Table 4.

9.6 X-ray tube assemblies

Duty cycle 1:8

Rectification type: Constant pot ential x-ray generator

Generator rating: Generator nominal power 1750W

Figure 1.3

Anode Thermal Characteristics

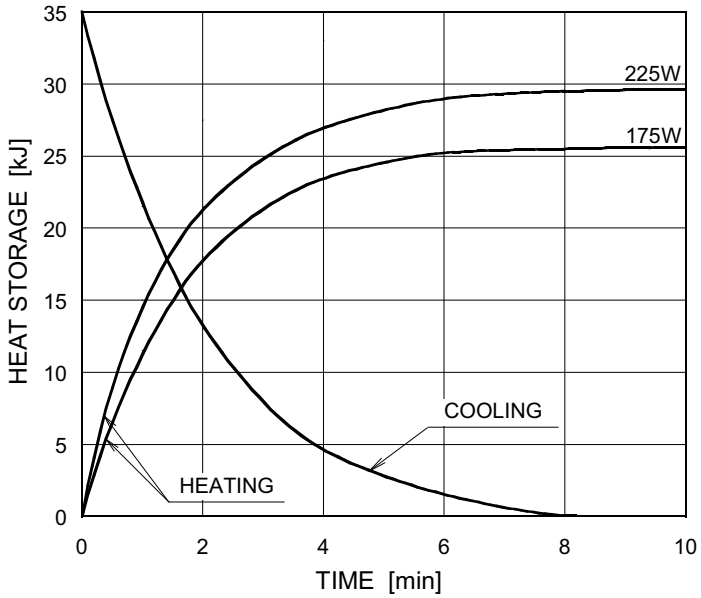


Figure 1.4

Maximum Rating Charts

(Absolute maximum rating charts)

DC (Center-Grounded)

Focal Spot : 0.5 mm

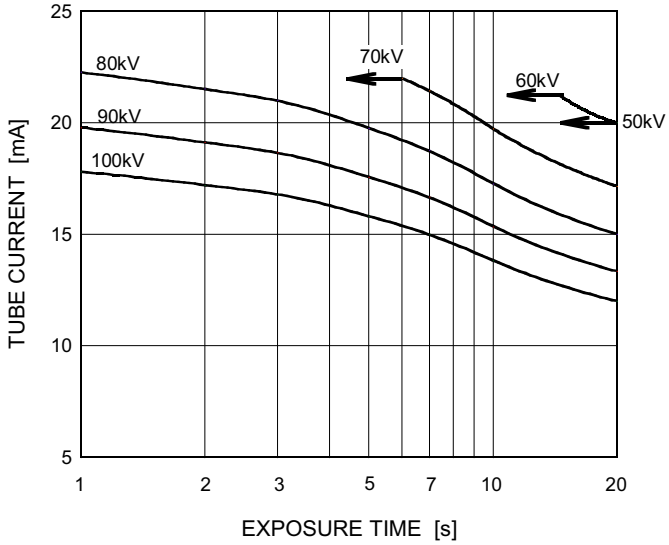
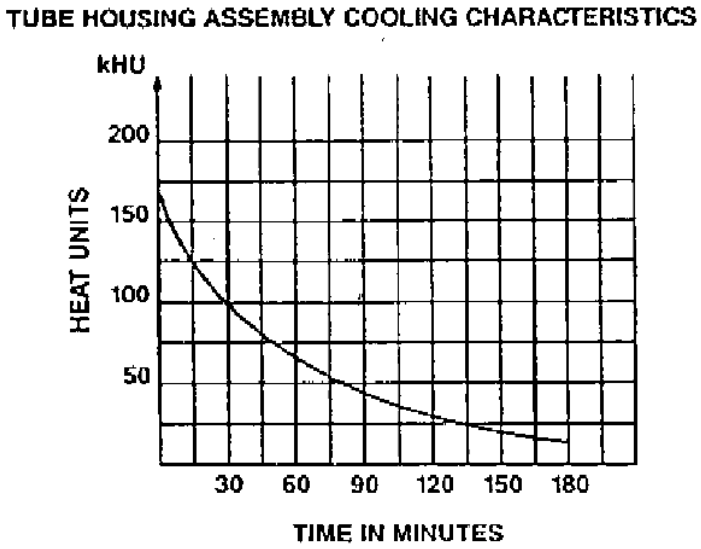


Figure 1.5


TUBE HOUSING ASSEMBLY COOLING CHARACTERISTICS
kHU
200
150
100
50
HEAT UNITS
30
60
90
120
150
180
TIME IN MINUTES